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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2016–0025]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security/ALL–030 Use of the Terrorist Screening Database System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Final rule.

SUMMARY: The Department of Homeland Security (DHS) is issuing a final rule to amend its regulations to exempt portions of an existing system of records titled, "Department of Homeland Security/ALL–030 Use of the Terrorist Screening Database System of Records" from certain provisions of the Privacy Act. Specifically, the Department exempts portions of the "Department of Homeland Security/ALL–030 Use of the Terrorist Screening Database System of Records" from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: This final rule is effective April 6, 2016.

FOR FURTHER INFORMATION CONTACT: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Homeland Security (DHS) published a notice of proposed rulemaking in the **Federal Register** at 81 FR 3758, on January 22, 2016, to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. DHS issued the "Department of Homeland Security/ALL–030 Use of the Terrorist Screening Database System of Records" in the **Federal Register** at 81 FR 3811 on January 22, 2016, to provide notice to the public that DHS was adding two new consumers to the "DHS Watchlist Service." DHS also clarified an existing category of individuals, added two new categories of individuals, and clarified the categories of records maintained in this system. DHS invited comments on both the Notice of Proposed Rulemaking (NPRM) and System of Records Notice (SORN).

II. Public Comments

DHS received three comments. Two comments were from private individuals who complemented DHS for this update. DHS received an identical comment from a public interest research center on the SORN and NPRM. The commenter raised concerns regarding the number of exemptions taken by DHS, particularly exemptions related to access and accounting for disclosures. Specifically, the commenter questioned the need to exempt records once an investigation was complete.

In response, DHS emphasizes that the Terrorist Screening Database (TSDB) belongs to the Department of Justice (DOJ)/Federal Bureau of Investigation (FBI). DHS does not change or alter these records. All records within the DHS/ALL–030 Use of the Terrorist Screening Database System of Records are collected and disseminated by the DOJ/FBI and are covered by the DOJ/FBI–019, "Terrorist Screening Records Center System," 72 FR 77846 (Dec. 14, 2011). Because DHS does not make any changes to the records obtained from DOJ/FBI, the same exemptions outlined in the DOJ/FBI SORN, and reasons provided in its implementing regulations for use of such exemptions at 28 CFR 16.96, transfer and apply. For instance, disclosing this information to individuals who have been misidentified as known or suspected terrorists due to a close name similarity, and of which the investigation has been completed, could reveal the Government's investigative interest in a terrorist suspect for an ongoing investigation, because it could make known the name of the individual who actually is the subject of the Government's interest. Similarly, providing any type of notice to a misidentified known or suspected terrorist due to a close name similarity could alert the actual known or suspected terrorist of the Government's investigative interest in that individual. Further, amendment of these records would impose an impossible administrative burden by requiring investigations, analyses, and reports to be continuously reinvestigated and revised. DHS is not taking any new exemptions as a result of the expansion to the categories of individuals in the TSDB. As noted in the NPRM, permitting access and amendment to watchlist records could disclose sensitive information that could be detrimental to national security. Release of the accounting of disclosures could reveal the details of watchlist matching measures, as well as capabilities and vulnerabilities of the watchlist matching process, the release of which could permit an individual to evade future detection and thereby impede efforts to ensure national security.

However, DHS does agree that some of the exemptions proposed in the NPRM are unnecessary. With the publication of this Final Rule, DHS is removing the exemption from subsections 5 U.S.C. 552a(e)(4)(G), (e)(4)(H), and (e)(4)(I) (Agency Requirements) and (f) (Agency Rules), because DHS has already established requirements, rules, or procedures with respect to individual access and will review each request for access on a case-by-case basis. Concurrent with this Final Rule, DHS is republishing the DHS/ALL–030 Use of the Terrorist Screening Database System of Records to reflect this change.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS amends chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: Pub. L. 107–296, 116 Stat. 2135; (6 U.S.C. 101 *et seq.*); 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. In appendix C to part 5, revise paragraph 66 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

■ 66. The DHS/ALL–030 Use of the Terrorist Screening Database System of Records consists of electronic and paper records and will be used by DHS and its Components. The DHS/ALL–030 Use of the Terrorist Screening Database System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, the enforcement of civil and criminal laws; investigations, inquiries, and proceedings thereunder; and national security and intelligence activities. The Terrorist Screening Database belongs to the Department of Justice (DOJ)/Federal Bureau of Investigation (FBI). DHS does not change or alter these records. All records within the DHS/ALL–030 Use of the Terrorist Screening Database System of Records are collected and disseminated by the DOJ/FBI and are covered by the DOJ/FBI–019, "Terrorist Screening Records Center System," 72 FR 77846 (Dec. 14, 2011). Because DHS does not make any changes to the records obtained from DOJ/FBI, the same exemptions outlined in the DOJ/FBI SORN, and reasons provided in its implementing regulations for use of such exemptions at 28 CFR 16.96, transfer and apply. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(j)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(5), (e)(8), and (g). When a record has been received from DOJ/FBI–019 Terrorist Screening Records System of Records and has been exempted in that source system, DHS will claim the same exemptions for those records that are claimed for that original primary system of records from which they originated and claims any additional exemptions set forth here. Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (d) (Access to Records) because access to the records contained in this system of records could inform the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS or another agency. Access to the records could permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension. Amendment of the records could interfere with ongoing investigations and law enforcement activities and would impose an unreasonable administrative burden by requiring investigations to be continually reinvestigated. In addition, permitting access and amendment to such information could disclose security-sensitive information that could be detrimental to homeland security.

(c) From subsection (e)(1) (Relevancy and Necessity of Information) because in the course of investigations into potential violations of Federal law, the accuracy of information obtained or introduced occasionally may be unclear, or the information may not be strictly relevant or necessary to a specific investigation. In the interests of effective law enforcement, it is appropriate to retain all information that may aid in establishing patterns of unlawful activity.

(d) From subsection (e)(2) (Collection of Information from Individuals) because requiring that information be collected from the subject of an investigation would alert the subject to the nature or existence of the investigation, thereby interfering with that investigation and related law enforcement activities.

(e) From subsection (e)(3) (Notice to Subjects) because providing such detailed information could impede law enforcement by compromising the existence of a confidential investigation or reveal the identity of witnesses or confidential informants.

(f) From subsection (e)(5) (Collection of Information) because with the collection of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely, and complete. Compliance with subsection (e)(5) would preclude DHS agents from using their investigative training and exercise of good judgment to both conduct and report on investigations.

(g) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(h) From subsection (g) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

* * * * *

Dated: March 22, 2016.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–07896 Filed 4–5–16; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2015–4010; Airspace Docket No. 15–ASO–11]

Establishment of Class D and Class E Airspace, and Amendment of Class E Airspace; Lake City, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class D airspace and Class E surface area airspace at Lake City, FL, providing the controlled airspace required for the Air Traffic Control Tower at Lake City Gateway Airport. This action also amends existing Class E airspace by recognizing the airport's name change. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at the airport. A minor adjustment is made to the geographic coordinates of the airport.

DATES: Effective 0901 UTC, May 26, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/airtraffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html*.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class D and Class E airspace, and amends Class E airspace at Lake City Gateway Airport, Lake City, FL.

History

On January 13, 2016, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to establish Class D airspace and Class E surface area airspace, and amend Class E airspace extending upward from 700 feet above the surface at Lake City Gateway Airport, Lake City, FL, providing the controlled airspace required to support the Air Traffic Control Tower (81 FR 1590) FAA–2015–4010. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, the FAA found an error in the geographic coordinates of Lake City Gateway Airport. This action corrects that error.

Class D and E airspace designations are published in paragraphs 5000, 6002, and 6005, respectively, of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class D airspace and Class E surface area airspace at Lake City Gateway Airport, Lake City, FL, providing the controlled airspace required to support the Air Traffic Control Tower. Class D airspace extending upward from the surface up to and including 2,500 feet is established within a 4.2 mile radius of the airport. Class E surface area airspace is established within a 4.2 mile radius of the airport. Class E airspace extending upward from 700 feet above the surface is amended by changing the airport's name from Lake City Municipal Airport to Lake City Gateway Airport. Controlled airspace is necessary for IFR operations. The geographic latitude coordinate of the airport is adjusted from "lat. 30°10′56″ N.", to "lat. 30°10′55″ N." for the Class D and E airspace areas.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Lake City, FL [New]

Lake City Gateway Airport, FL
(Lat. 30°10′55″ N., long. 82°34′37″ W.)

That airspace extending upward from the surface to and including 2,500 feet within a 4.2-mile radius of Lake City Gateway Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6002 Class E Surface Area Airspace.

* * * * *

ASO FL E2 Lake City, FL [New]

Lake City Gateway Airport, FL
(Lat. 30°10′55″ N., long. 82°34′37″ W.)

Within a 4.2-mile radius of Lake City Gateway Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO FL E5 Lake City, FL [Amended]

Lake City Gateway Airport, FL
(Lat. 30°10′55″ N., long. 82°34′37″ W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Lake City Gateway Airport.

Issued in College Park, Georgia, on March 29, 2016.

Ryan W. Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2016–07782 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–4239; Airspace Docket No. 16–ASO–4]

Amendment of Class D Airspace for Bartow, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D Airspace at Bartow Municipal Airport, Bartow, FL, by adjusting the ceiling of the Class D airspace area from 2,600 feet to 1,600 feet above the surface. This change allows the air traffic control tower at Tampa International Airport, Tampa, FL, to carry out Letter of Agreement procedures, already established, between Bartow Air Traffic Control Tower and Tampa Terminal Radar Approach Control (TRACON) for the safety and management of standard instrument approach procedures (SIAPs) and for Instrument Flight Rule (IFR) operations in the area.

DATES: Effective 0901 UTC, May 26, 2016. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/airtraffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call 202–741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class D airspace at Bartow Municipal Airport, Bartow, FL.

History

In a review of the airspace, the FAA found the Class D airspace description for Bartow Municipal Airport, Bartow, FL, published in FAA Order 7400.9Z, describes the ceiling as, extending upward from the surface to and including 2,600 feet MSL. The Tampa International Airport Class B airspace area has control of aircraft operating at and above 1,800 feet MSL in the Bartow, FL, Class D airspace area. The FAA is lowering the Class D airspace area to 1,600 feet MSL to avoid the overlap between the two facilities. To avoid confusion on the part of the pilots overflying the Bartow, FL, area, the FAA finds that notice and public procedure under 5 U.S.C 553(b) are impracticable and contrary to the public interest. To be consistent with the FAA's safety mandate when an unsafe condition exists, the FAA finds good cause pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days to promote the safe and efficient handling of air traffic in the area.

Class D airspace designations are published in paragraphs 5000 of FAA Order 7400.9Z dated August 6, 2015, and effective September 15, 2015, which is incorporated by reference in 14 CFR part 71.1. The Class D airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by lowering the Class D ceiling airspace area from 2,600 feet MSL to and including 1,600 feet MSL at Bartow Municipal Airport, Bartow, FL. The Letter of Agreement between Tampa TRACON and Bartow ATCT, established June 3, 2013, states that Tampa TRACON shall control aircraft operating at or above 1,800 feet MSL in the Bartow Airport Class D airspace area. This airspace change eliminates pilot confusion for those aircraft operating above 1,600 feet MSL in the Bartow Airport Class D airspace area.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, effective September 15, 2015, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Bartow, FL [Amended]

Bartow Municipal Airport, FL
(Lat. 27°56′36″ N., long. 81°47′00″ W.)

That airspace extending upward from the surface to and including 1,600 feet MSL within a 4-mile radius of Bartow Municipal Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

Issued in College Park, Georgia, on March 29, 2016.

Ryan W. Almasy,

Manager, Operations Support Group Eastern Service Center, Air Traffic Organization.

[FR Doc. 2016–07783 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No.: FAA–2008–0221]

Change of Newark Liberty International Airport (EWR) Designation

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Change of Newark Liberty International Airport (EWR) Designation.

SUMMARY: This document announces that the FAA will designate Newark Liberty International Airport (EWR) as a Level 2, schedule-facilitated airport under the International Air Transport Association (IATA) Worldwide Slot Guidelines (WSG) effective for the Winter 2016 scheduling season, which begins on October 30, 2016. The FAA has determined this designation is necessary based on an updated demand and capacity analysis of the airport. The current FAA Order designating EWR as a Level 3, slot-controlled airport will expire on October 29, 2016.

DATES: This designation takes effect on October 30, 2016.

ADDRESSES: Requests may be submitted by mail to Slot Administration Office, AGC–220 Office of the Chief Counsel, 800 Independence Ave. SW., Washington, DC 20591; facsimile: 202–267–7277; or by email to: *7-AWA-slotadmin@faa.gov.*

FOR FURTHER INFORMATION CONTACT: For questions contact: Susan Pfingstler, System Operations Services, Air Traffic Organization, Federal Aviation Administration, 600 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–6462; email *susan.pfingstler@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

By Order dated May 21, 2008, the FAA placed temporary limits on scheduled operations at EWR to mitigate congestion and delays at the airport.[1] The Order addressed the FAA's concern about a spillover effect in the summer 2008 scheduling season resulting from the Agency's Order limiting operations at John F. Kennedy International Airport (JFK), which took effect in March 2008.[2]

Under the EWR Order, the FAA (1) established hourly limits of 81 scheduled operations during the peak period; (2) imposed an 80 percent minimum usage requirement for Operating Authorizations (OAs or slots) with defined exceptions; (3) provided a mechanism for withdrawal of OAs for FAA operational reasons; (4) established procedures to allocate withdrawn, surrendered, or unallocated OAs; and, (5) allowed for trades and leases of OAs for consideration for the duration of the Order.

On January 8, 2015, the Department of Transportation (DOT) and FAA issued the Slot Management and Transparency for LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport Notice of Proposed Rulemaking (NPRM).[3] The DOT and FAA are currently reviewing the comments received on the NPRM and considering the impacts of the EWR Level 2 designation on the rulemaking.

Based on the FAA's review of operational performance, demand, and capacity discussed in this document, Level 3 slot controls are no longer warranted for EWR. Rather, the FAA will transition EWR to a Level 2, schedule-facilitated airport, starting with the Winter 2016 scheduling season. In addition, the FAA also has updated the performance, demand, and capacity analyses for JFK and LGA and has determined that Level 3 slot-controlled restrictions remain necessary for these airports. Therefore, through separate notices published in the **Federal Register**, the FAA will be extending the JFK and LGA Orders until October 27, 2018.

This document confirms the EWR Order will expire on October 29, 2016. A copy of this document will be placed in Docket FAA–2008–0221. As explained herein, the FAA is designating EWR as a Level 2 airport effective October 30, 2016. As further explained in this document, the FAA has conducted a screening for potential impacts to noise and air emissions as a result of this change in designation at EWR and has determined that the proposed action does not have the potential to cause a significant impact.

Capacity and Operational Performance Review

The FAA regularly reviews operational performance and demand at the New York City area airports as part of ongoing efforts to improve the efficiency of the air traffic control system. Section 413 of the FAA Modernization and Reform Act, Pub. L. 112–95, 126 Stat. 11 (Feb. 14, 2012), requires the FAA to take actions to ensure that aircraft operations of air carriers do not exceed the hourly maximum departure and arrival rate established by the Administrator for such operations. The FAA reviews data on actual operations, including the number of hourly and daily air traffic operations, runway capacity and utilization, aircraft fleet mix, scheduled and unscheduled demand, on-time performance relative to schedule, the number and duration of flight arrival and departure delays, airfield or other capacity changes, and air traffic control procedures.

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[1] 73 FR 29550 (May 21, 2008).

[2] 73 FR 3510 (Jan. 18, 2008).

[3] 80 FR 1274.

On an annual basis since adopting the 2008 Order, the FAA has performed analyses to compare and contrast operational and performance data for each year subsequent to the peak 2007 summer scheduling season to identify operational and performance trends. Such analyses have consistently placed particular emphasis on the May through August months since this period includes the peak summer demand. The on-time performance and delay metrics at EWR show significant improvements during such peak periods of demand. For example, on-time gate arrivals at EWR have increased by about 11 percentage points when comparing May through August 2015 to the same period in 2007.[4] On-time gate departures improved by approximately three percentage points. The mean arrival and departure delays are down by about 33 percent, and the delays greater than 60 minutes are down by 37 percent for arrivals and 38 percent for departures.

The FAA recently modeled the summer 2015 demand against summer 2015 runway capacity and then compared the results to the delay profile that was the basis for the 2008 Order. Operations in 2015 were down by 8 percent, total minutes of arrival delays went from 16,100 to 10,100 for a 37 percent decrease, mean arrival delays decreased from 24.0 minutes to 16.3 minutes, and mean departure delays from 18.0 minutes to 14.2 minutes.[5]

The FAA also reviewed scheduled flights at EWR over the last few years. Scheduled demand was routinely below the 81 hourly scheduling limits in the Order, even during the busiest early morning, afternoon, and evening hours. For example, in the 3 p.m. through 8:59 p.m. local hours, weekday scheduled demand in the May-August period averaged 71 flights per hour in 2011, 74 flights per hour in 2013, and 72 flights per hour in 2015.[6] Early summer 2016 schedules reflect similar demand patterns. At the same time, the FAA denied requests for new flights as slots are allocated up to the scheduling limits. Carriers are generally maintaining historic slots and meeting the minimum usage rules under the Order; therefore, weekday slots in peak hours do not regularly revert to the FAA for reallocation. The result is scheduled demand that is well below the FAA scheduling limits and runway capacity at the airport to handle additional flights. This is unlike other FAA slot-controlled airports, which have significantly fewer differences between the number of allocated slots and the scheduled demand, especially in peak periods.

FAA Level 2 Determination and Planned Schedule Review

In light of the FAA's demand and capacity analysis at EWR, the FAA has determined that EWR does not warrant a Level 3 designation. The FAA's analysis demonstrates that runway capacity exists for additional operations. However, under a Level 3 designation, the FAA must deny requests from carriers to add or retime operations based on allocated slots rather than scheduled and actual operations, provided the carrier satisfies the minimum slot usage requirements. Further, the FAA simply cannot increase the scheduling limits to compensate for slots that are under-scheduled but meet the minimum usage rules, as this would require the FAA to determine that additional capacity exists for operations above the current scheduling limits.

The FAA also considered whether EWR should be re-designated as a Level 1 airport since EWR operated for many years without scheduling limits while nearby JFK and LGA were slot controlled. During this time, EWR provided access to the New York City area and, while delays were high compared to other airports, overall demand was generally consistent with runway capacity. However, there are practical limitations to the number of additional flights that EWR can accept from a runway and airport facilities perspective. Moreover, we expect there will be significant demand for access to EWR, given its location and that the JFK and LGA airports will remain slot-controlled airports. Thus, the FAA has determined that the Level 2 schedule facilitation process and its related principles of voluntary cooperation will best balance the anticipated demand with the practical limitations on the number of additional flights possible at EWR. Following the effective date of the Level 2 designation, the FAA will continue to review whether Level 2 is appropriate or whether other action might be needed. The FAA does not expect to make any airport level changes based on short-term airline schedule plans or resulting delays.

Consistent with existing FAA practice for schedule facilitation at Level 2 airports, under the Level 2 designation at EWR, the FAA will request and review airline schedules for the 6 a.m. to 10:59 p.m. period and either approve the request or work with carriers to achieve schedule adjustments as needed to avoid exceeding the airport's capacity. The success of Level 2 schedule facilitation procedures depends upon a number of factors delineated in the WSG. The FAA will apply the priorities for schedule facilitation outlined in the WSG. In particular, priority will be given to carriers based on actual approved schedules and operations conducted in the previous corresponding season over new demand for the same timings.

Additionally, although there is some runway capacity available at EWR, approval of new or retimed operations must avoid significant scheduled peaking and allow for recovery to avoid causing a consistent level of unacceptable delay, which could necessitate a return to Level 3. The FAA intends, if necessary, to deny schedule submissions that exceed the declared airport runway capacity and to offer alternative times to carriers. The WSG recognizes that some carriers might operate at times without approval from the airport's schedule facilitator. Consistent with the WSG, carriers would not receive historic status for such flights if the airport level changes from Level 2 to Level 3.

Finally, while the FAA is responsible for managing the airport's runway capacity, there are terminal, gate, and other operational factors that may require schedule adjustments. The FAA recognizes that the entry at EWR has been limited by runway slot availability for the last 8 years and new entry and growth by incumbent carriers is expected. The Port Authority of New York and New Jersey (Port Authority) currently reviews schedules for international passenger flights operating at Terminal B. A carrier must separately obtain approval from the Port Authority for Terminal B flights and request runway slots from the FAA under the current Level 3 designation Order. After the effective date for the Level 2 designation, carriers would continue to work with the Port Authority to synchronize with the relevant terminals and gates at EWR to the extent practicable. Under existing practice, the FAA regularly works with the Port Authority and carriers to reconcile differences between available terminal/gate and runway times. The FAA expects this process to continue under the Level 2 designation based on impacts to the availability of facilities. This necessary de-conflicting of carriers' requested terminal/gate and runway schedules is likely to be most significant in the initial transition from Level 3 to Level 2 in the Winter 2016 and Summer 2017 seasons.

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[4] On-time gate arrivals have a gate arrival delay of less than 15 minutes. The gate arrival delay is the difference in minutes between the actual time the aircraft arrives at the gate and the scheduled gate arrival time.

[5] A copy of the MITRE summary of performance comparing 2015 and 2007 has been placed in the dockets for the EWR Order (Docket No. FAA–2008–0221), JFK Order (Docket No. FAA–2007–29320), LGA Order (Docket No. FAA–2006–25755) and the Slot Management and Transparency for LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport NPRM (Docket No. FAA–2014–1073).

[6] There are a few additional flights by carriers such as FedEx and UPS that are allocated slots and do not publish schedules in the FAA's Innovata schedule database.

Environmental Considerations

The FAA conducted an environmental screening for potential impacts to noise and air emissions relative to the change of the EWR designation from Level 3 to Level 2. Based on the screening, the FAA has determined that this action may be categorically excluded from further environmental analysis according to FAA Order 1050.1, "Environmental Impacts: Policies and Procedures," paragraph 5–6.6.f. Specifically, paragraph 5–6.6.f states that "Regulations, standards, and exemptions (excluding those which if implemented may cause a significant impact on the human environment)" are categorically excluded from further environmental review.

The FAA conducted noise screening of the proposed action using Area Equivalent Method and determined that the action does not have the potential to cause a significant impact on noise levels of noise sensitive areas. In addition, the FAA conducted an analysis of air emissions using Aviation Environmental Design Tool and determined that the action does not have the potential to cause a significant impact on air quality or a violation of Federal, state, tribal, or local air quality standards under the Clean Air Act, 42 U.S.C. §§ 7401–7671q. Therefore, implementation of the airport level change is not expected to result in significant adverse impacts to the human environment. The implementation of this action is not expected to result in any extraordinary circumstances in accordance with FAA Order 1050.1. A copy of the categorical exclusion has been placed in the docket associated with this action.

Future Operational Demand and Performance Reviews

The FAA will continue to regularly review and monitor performance at EWR, as well as carrier compliance with FAA-approved schedules. The FAA will continue to review data on actual operations, including the number of hourly and daily air traffic operations, runway capacity and utilization, aircraft fleet mix, scheduled and unscheduled demand, on-time performance relative to schedule, the number and duration of flight arrival and departure delays, airfield or other capacity changes, and air traffic control procedures. The FAA will publish a notice in April, 2016 announcing the schedule submission deadline and the declared runway capacity limits for the Winter 2016 scheduling season.

The FAA expects that delays at EWR will increase over current levels as flights are added, but an incremental increase in delays would not necessarily mean the FAA would revert to Level 3. The FAA's objective while working with carriers under the Level 2 process is to appropriately balance and maximize the use of the available runway capacity at EWR while maintaining an acceptable level of delay.

Issued in Washington, DC on April 1, 2016.

Daniel E. Smiley,

Acting Vice President, System Operations Services.

[FR Doc. 2016–07910 Filed 4–1–16; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF STATE

22 CFR Part 171

RIN 1400–AD44

[Public Notice: 9510]

Public Access to Information

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (the Department) finalizes its revisions to its regulations implementing the Freedom of Information Act (FOIA) and the Privacy Act. The final rule reflects changes in FOIA and other statutes and consequent changes in the Department's procedures since the last revision of the Department's regulations on this subject.

DATES: This rule is effective on May 6, 2016.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Office of the Legal Adviser, Office of Management, U.S. Department of State, *kottmyeram@state.gov,* (202) 647–2318.

SUPPLEMENTARY INFORMATION: On July 28, 2015, the Department published a notice of proposed rulemaking (NPRM) to update its FOIA and Privacy Act rules contained in 22 CFR part 171. See 80 FR 44898, and the discussion therein.

This rulemaking responds to public comments and finalizes the rule. The rule is finalized as published in the NPRM, except for minor format edits; modifications, as indicated below, in response to public comments; and the addition of one clause to § 171.24(a), which codifies a longstanding provision of the Privacy Act (5 U.S.C. 552a(c)(3)), and which was inadvertently omitted from the NPRM. Since § 171.24(a) is substantially the same as 5 U.S.C. 552a(c)(3) in the Privacy Act itself, it need not be published for comment.

Response to Public Comments

The Department would like to thank the members of the public who invested time in reviewing the proposed changes to the FOIA and Privacy Act regulations, and for providing very useful feedback.

First Public Comment

The first commenter expressed concern about the proposal for the Department to charge a fee of 15 cents per page of duplication. The commenter pointed out that present day photocopying and scanning is relatively cheap, and expressed a belief that the Department's lease arrangements reflect a significantly lesser per page cost than 15 cents; in addition, he stated that other agencies' costs vary and might be lower, and no evidence was provided on how the Department formulated the fee. He stated that some other agencies have lowered duplication costs in their regulations in the last two years to be in line with actual direct costs.

Department Response

The fee charged for photocopying at the Department is 15 cents per page, which is charged at a standard rate throughout the Department for copying services. This charge is based on the costs calculated by examining paper costs, machinery, and services provided to produce a photocopy. Other agencies and departments charge FOIA duplication fees that range from five cents to twenty cents per page. The Department's duplication fee of fifteen cents per page is in line with what other agencies and departments charge for duplication. For this reason, the Department declines to change the duplication fee as suggested.

Second Public Comment

This comment expressed the following six points:

1. In proposed § 171.11, Processing requests, the proposed regulations state that a requester "shall be considered to have agreed to pay applicable fees up to $25, unless a fee waiver is granted." The commenters believe that the Department should follow Department of Justice's regulations and provide that no fees will be assessed if the fees are under $25, which is their approximate cost of collecting fees. Also, they believe the Department should at least limit the presumption to instances in which a fee waiver has not been requested, per the Department of Justice's superseded regulations.

Department Response to Point 1

The Department accepts the Justice Department's estimate that the cost to collect fees is approximately $25.00. The Department agrees to revise § 171.14, "Fees to be charged," to state the current cost of collecting a fee is $25.00; therefore, the Department will process requests without assessing fees up to $25.00. The Department will also revise this section to state that the Department will attempt to notify the requester if fees are estimated to exceed $25.00, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated.

2. In proposed § 171.11(f), the commenters are concerned that the appeal of expedited processing is submitted to the Director of IPS, the same Director who is responsible for issuing initial determinations on requests. The regulations should clearly state if the Director is receiving the appeals on behalf of the Appeal Review Panel.

Department Response to Point 2

The Department's Appeals Review Panel does not review appeals from denials of expedited processing. See 22 CFR 171.13(a). For this reason, the Department will not revise § 171.11(f) as suggested. The Department will revise § 171.11(a) to state that the Division Chief, Requester Liaison Division, in the Office of Information Programs and Services, will issue all initial decisions on whether a request is valid or perfected, and whether to grant or deny requests for a fee waiver and for expedited processing.

3. The acknowledgement letter in subsection (i) should include the receipt date, to assist requesters with determining an agency's statutory response deadline.

Department Response to Point 3

The Department will revise § 171.11(e), "Receipt of request", to include a subsection that states that upon receipt IPS will send an acknowledgement letter to the requester that will identify the date of receipt of the request in the proper component, as identified in § 171.11(a), and the case tracking number. Subsection (i) sets forth the information that is available to a requester by contacting the FOIA Requester Service Center.

4. The Department's proposed consultation procedures in subsection (m) are limited to agencies only. They do not account for consultations that may be required with the Office of the White House Counsel. The commenters believe the regulations should address its FOIA-related consultations with the Office of White House Counsel.

Department Response to Point 4

Section 171.11(m) "Referrals and Consultations" states that the Department will refer documents created by another agency to that agency for a release determination. In practice, the implementation of this section turns on the identity of the originator of a document and not on whether the originator works in an agency or department or other governmental entity. The Department will revise subsection (m) as follows: "If the Department determines that Department records retrieved as responsive to the request are of interest to another agency or Federal government office, it may consult with the other agency or office before responding to the request."

5. Business information. The Department should specify a minimum number of days that submitters will have to provide comments and to file a "reverse-FOIA" lawsuit, respectively. This is preferred over a "reasonable period of time". The commenters recognize that circumstances might warrant providing one submitter with more time than another. They believe five business days would be considered a "reasonable period of time," as Executive Order 12600 requires.

Department Response to Point 5

The Department declines to revise this subsection as suggested, because providing some flexibility to submitters in seeking input in response to a notice issued under this subsection ensures the best outcome for the requesters, the submitters, and the Department.

6. In § 171.16, Waiver or reduction of fees, the commenters are concerned with the Department responding to fee waiver appeals within "30 working days" from the date of receipt. Unless unusual circumstances exist, an agency must make a determination on a fee waiver appeal within 20 working days. Furthermore, they ask for clarification on who will adjudicate the fee waiver appeals, as it is presumably not the "Director of IPS" who issues fee determinations.

Department Response to Point 6

The Department will revise § 171.16(e) to state that the Department must respond to an appeal of a denial of a fee waiver or fee reduction request within 20 working days. The Department's Appeals Review Panel does not review appeals from a denial of a fee waiver. See 22 CFR 171.13(a). The Department will revise § 171.16 (e) to state that the Division Chief of the Requester Liaison Division in IPS will issue all initial decisions on whether to grant or deny requests for a fee waiver and that appeals should be directed to the Director of IPS.

Third Public Comment

The third public comment was submitted by the National Archives and Records Administration's Office of Government Information Services (OGIS). OGIS suggested adding to the end of § 171.13(d) the following or similar language: "If the requester elects to engage in the mediation services offered by the Office of Government Information Services of the National Archives and Records Administration, the Department of State must actively engage as a partner to the mediation process in an attempt to resolve the dispute."

Department Response

The Department understands the importance of resolving disputes between FOIA requesters and Federal agencies, and will revise this subsection as follows: "When the Department of State engages in the mediation services offered by OGIS, it will work in good faith as a partner to the mediation process in an attempt to resolve the dispute. The Department reserves its right to decide on a case-by-case basis whether to enter into formal mediation offered by OGIS."

Fourth Public Comment

This comment, from Cause of Action, suggests that the Department revise its definition of a representative of the news media, following an opinion of the District of Columbia Circuit Court in *Cause of Action* v. *Federal Trade Commission.* While the Department's proposed rule states that those requesting news media status "make their products available to the general public," Cause of Action requests that the Department include a non-exhaustive list of the methods an agency must consider when analyzing this element of the test, including: "newsletters, press releases, press contacts, a Web site, and planned reports."

Furthermore, Cause of Action raised concern over the "middleman standard" not being included in the Department's regulatory definition. Cause of Action stated that the D.C. Circuit Court "disagreed with the suggestion that a public interest advocacy organization cannot satisfy the statute's distribution criterion because it is 'more like a middleman for dissemination to the media than a representative of the media itself'. . . There is no indication that Congress meant to distinguish between those who reach their ultimate audiences directly and those who partner with others to do so." Cause of Action believes that the final rule should draw a distinction between those that market FOIA information for their direct economic benefit and the Court's direction that "public interest advocacy organizations" can "partner with others" to disseminate their distinct works.

Department Response

The regulation states that the examples provided regarding who may qualify for news media status are not all-inclusive; therefore, the Department does not believe that providing another non all-inclusive list would help shed light on the process the Department employs.

The Department agrees that this information may be helpful for requesters to understand how IPS analyzes a request for representative in the news media status. For this reason, the Department will add this information to its public FOIA Web site.

In the second comment (regarding the "middleman standard"), the Office of Management and Budget ("OMB") has policy-making responsibility for issuing fee guidance. For this reason, the Department defers to OMB with regard to this suggestion.

Regulatory Findings

Administrative Procedure Act

The Department published this rule under the provisions of 5 U.S.C. 553, with a 60-day public comment period.

Regulatory Flexibility Act

The Department of State, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and import markets.

Executive Order 12988—Civil Justice Reform

The Department has reviewed this regulation in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Orders 12372 and 13132—Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this regulation.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Executive Orders 12866 and 13563—Improving Regulation and Regulatory Review

The Department has considered this rule in light of these Executive Orders and affirms that this regulation is consistent with the guidance therein. The benefits of this rulemaking for the public include, but are not limited to, providing an up-to-date procedure for requesting information from the Department. The Department is aware of no cost to the public from this rulemaking.

Paperwork Reduction Act

This rule does not impose or revise any reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 171

Administrative practice and procedure, Freedom of information, Privacy.

For the reasons set forth in the preamble, 22 CFR part 171 is revised to read as follows:

PART 171—PUBLIC ACCESS TO INFORMATION

Subpart A—General Policy and Procedures

Sec.
171.1 General provisions.
171.2 Types of records maintained.
171.3 Records available on the Department's Web site.
171.4 Requests for information—types and how made.
171.5 Archival records.

Subpart B—Freedom of Information Act Provisions

171.10 Purpose and scope.
171.11 Processing requests.
171.12 Business information.
171.13 Appeal of denial of request for records.
171.14 Fees to be charged.
171.15 Miscellaneous fee provisions.
171.16 Waiver or reduction of fees.
171.17 Resolving disputes.
171.18 Preservation of records.

Subpart C—Privacy Act Provisions

171.20 Purpose and scope.
171.21 Definitions.
171.22 Request for access to records.
171.23 Request to amend or correct records.
171.24 Request for an accounting of record disclosures.
171.25 Appeals from denials of PA amendment requests.
171.26 Exemptions.

Subpart D—Process To Request Public Financial Disclosure Reports

171.30 Purpose and scope.
171.31 Requests.

Authority: 22 U.S.C. 2651a; 5 U.S.C. 552, 552a; E.O. 12600 (52 FR 23781); Pub. L. 95–521, 92 Stat. 1824 (codified as amended at 5 U.S.C. app. 101–505); 5 CFR part 2634.

Subpart A—General Policy and Procedures

§ 171.1 General provisions.

(a) This subpart contains the rules that the Department of State and the Foreign Service Grievance Board (FSGB), an independent body, follow in processing requests for records under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, and the Privacy Act of 1974 (PA), 5 U.S.C. 552a, as amended. Records of the Department shall be made available to the public upon request made in compliance with the access procedures established in this part, except for any records exempt by law from disclosure. Regulations at 22 CFR 172.1 through 172.9 govern, *inter alia,* the service of subpoenas, court orders, and other demands or requests for official Department information or action, as well as the Department's response to demands or requests for official Department information or action in connection with legal proceedings in the United States to which the Department is not a party.

(b) *Definitions.* (1) For purposes of subparts A, B, and D of this part, *record* means information regardless of its physical form or characteristics—including information created, stored, and retrievable by electronic means—that is created or obtained by the Department and under the control of the Department at the time of the request, including information maintained for the Department by an entity under Government contract for records management purposes. It does not include records that are not already in existence and that would have to be created specifically to respond to a request. Information available in electronic form shall be searched and compiled in response to a request unless such search and compilation would significantly interfere with the operation of the Department's automated information systems.

(2) For purposes of subparts A, B, C, and D of this part, *Department* means the United States Department of State, including its field offices and Foreign Service posts abroad.

§ 171.2 Types of records maintained.

Most of the records maintained by the Department pertain to the formulation and execution of U.S. foreign policy. The Department also maintains certain records that pertain to individuals, such as applications for U.S. passports, applications for visas to enter the United States, records on consular assistance given abroad by U.S. Foreign Service posts to U.S citizens and legal permanent residents, and records on Department employees. Further information on the types of records maintained by the Department may be obtained by reviewing the Department's records disposition schedules, which are available on the Department's Web site at *www.foia.state.gov.*

§ 171.3 Records available on the Department's Web site.

Information that is required to be published in the **Federal Register** under 5 U.S.C. 552(a)(1) is regularly updated by the Department and found on its public Web site: *www.state.gov.* Records that are required by the FOIA to be made available for public inspection and copying under 5 U.S.C. 552(a)(2) also are available on the Department's public Web site. Included on the Department's FOIA home page, *www.foia.state.gov,* are links to other sites where Department information may be available, links to the Department's PA systems of records, and the Department's records disposition schedules. Also available on the FOIA Web site are certain records released by the Department pursuant to requests under the FOIA and compilations of records reviewed and released in certain special projects. In addition, see 22 CFR part 173 regarding materials disseminated abroad by the Department.

§ 171.4 Requests for information—types and how made.

(a) Requests for records made in accordance with subparts A, B, and C of this part must be made in writing and may be made by mail addressed to the Office of Information Programs and Services (IPS), U.S. Department of State, State Annex 2 (SA–2), 515 22nd Street, NW., Washington, DC 20522–8100, or by fax to (202) 261–8579, or through the Department's FOIA Web site (*www.foia.state.gov*). PA requests may be made by mail or fax only. IPS does not accept requests submitted by email.

(1) Requests for passport records that are covered under PA System of Records Notice 26, including passport records issued from 1925 to present, should be mailed to U.S. Department of State, Law Enforcement Liaison Division, CA/PPT/S/L/LE, 44132 Mercure Cir, P.O. Box 1227, Sterling, VA 20166. Further guidance on obtaining passport records is available on the Department's Web site: *travel.state.gov/content/passports/english/passports/services/obtain-copies-of-passport-records.html.*

(2) Requests for records of the Office of Inspector General (OIG) may be submitted to U.S. Department of State, Office of Inspector General, Office of General Counsel, Washington, DC 20520–0308, ATTN: FOIA officer. In addition, FOIA requests seeking OIG records may be submitted via email to *oigfoia@state.gov,* which is preferred. PA requests are accepted by mail only. Guidance is available on the OIG's Web site: *oig.state.gov/foia/index.htm.*

(3) All other requests for other Department records must be submitted to the Office of Information Programs and Services by one of the means noted above. The Office of Information Programs and Services, the Law Enforcement Liaison Division of the Office of Passport Services, and the OIG are the only Department components authorized to accept FOIA requests submitted to the Department.

(4) Providing the specific citation to the statute under which a requester is requesting information will facilitate the processing of the request by the Department. The Department automatically processes requests for information maintained in a PA system of records under both the FOIA and the PA to provide the requester with the greatest degree of access to the requester. Such information may be withheld only if it is exempt from access under both laws; if the information is exempt under only one of the laws, it must be released.

(b) Although no particular format is required, a request must reasonably describe the Department records that are sought. To the extent that requests are specific and include all pertinent details about the requested information, it will be easier for the Department to locate responsive records. For FOIA requests, such details include the subject, timeframe, names of any individuals involved, a contract number (if applicable), and reasons why the requester believes the Department may have records on the subject of the request.

(c) While every effort is made to guarantee the greatest possible access to all requesters regardless of the statute(s) under which the information is requested, the following guidance is provided for the benefit of requesters:

(1) The Freedom of Information Act applies to requests for records concerning the general activities of government and of the Department in particular (see subpart B of this part).

(2) The Privacy Act applies to requests from U.S. citizens or legal permanent resident aliens for records that pertain to them that are maintained by the Department in a system of records retrievable by the individual's name or personal identifier (see subpart C of this part).

(d) As a general matter, information access requests are processed in the order in which they are received. However, if the request is specific and the search can be narrowed, it may be processed more quickly. Additionally, FOIA requests granted expedited processing will be placed in the expedited processing queue (see § 171.11(f) for more information). Multi-tracking of FOIA requests is also used to manage requests (see § 171.11(h)).

§ 171.5 Archival records.

The Department ordinarily transfers records designated as historically significant to the National Archives when they are 25 years old. Accordingly, requests for some Department records 25 years old or older should be submitted to the National Archives by mail addressed to Special Access and FOIA Staff (NWCTF), 8601 Adelphi Road, Room 5500, College Park, MD 20740; by fax to (301) 837–1864; or by email to *specialaccess_foia@nara.gov.* The Department's Web site, *www.foia.state.gov,* has additional information regarding archival records.

Subpart B—Freedom of Information Act Provisions

§ 171.10 Purpose and scope.

This subpart contains the rules that the Department follows under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended. The rules should be read together with the FOIA, which provides additional information about access to records and contains the specific exemptions that are applicable to withholding information, the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget (OMB Guidelines), and information located at *www.foia.state.gov.* The Department processes records maintained in a Privacy Act (PA) system of records that are determined to be exempt from disclosure under the PA under the FOIA as well. As a result, requests that seek such records are also subject to this subpart.

§ 171.11 Processing requests.

(a) *In general.* (1) Subject to paragraph (a)(2) of this section, the Director of the Office of Information Programs and Services (IPS) is responsible for initial action on all FOIA requests for Department records with two exceptions: Requests submitted directly to the Office of Inspector General (OIG), which receives and processes requests for OIG records; and the Office of Passport Services in the Bureau of Consular Affairs (PPT), which receives and processes requests for passport records (see § 171.4(a)). Once received by IPS, all requests for records coming under the jurisdiction of the following bureaus or offices are processed by those bureaus, although IPS may provide review and coordination support to these bureaus/offices in some situations: the Bureau of Consular Affairs' Office of Visa Services, Office of Passport Services (except for information identified in § 171.4(a)), and Office of Overseas Citizens Services; the Bureau of Diplomatic Security; the Bureau of Human Resources; the Office of Medical Services; and the Foreign Service Grievance Board (FSGB). Additionally, the FSGB, as an independent body, processes all FOIA requests seeking access to its records and responds directly to requesters.

(2) The Division Chief, Requester Liaison Division, in the Office of Information Programs and Services, shall issue all initial decisions on whether a request is valid or perfected, and whether to grant or deny requests for a fee waiver or for expedited processing.

Definitions. The following definitions apply for purposes of this section:

(1) *Control* means the Department's legal authority over a record, taking into account the ability of the Department to use and dispose of the record, the intent of the record's creator to retain or relinquish control over the record, the extent to which Department personnel have read or relied upon the record, and the degree to which the record has been integrated into the Department's record-keeping systems or files.

(2) *Urgently needed information.* The information has a particular value that will be lost if not disseminated quickly. Ordinarily this means a breaking news story of general public interest. Information of historical interest only or information sought for litigation or commercial activities would not generally qualify, nor would a news media publication or broadcast deadline unrelated to the breaking nature of the story.

(3) *Actual or alleged Federal government activity.* The information concerns actual or alleged actions taken or contemplated by the government of the United States, or by one of its components or agencies, including the Congress.

(4) *Unusual circumstances* means:

(i) The need to search for and collect the requested records from Foreign Service posts or Department offices other than IPS;

(ii) The need to search for, collect, and appropriately examine a voluminous amount of distinct records; or

(iii) The need to consult with another agency or other agencies that has/have a substantial interest in the records, or among two or more Department components that have a substantial subject-matter interest therein. In the majority of requests received by the Department unusual circumstances exist due to the need to search in multiple bureaus/offices/posts located around the globe.

(c) *Form of request and response.* A requester may ask for any information he or she believes the Department has in its possession or control. The requester must describe the records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. The more specific the information the requester furnishes, the more likely that Department personnel will be able to locate responsive records if they exist. Any records provided in response to a request shall be provided in the form or format requested if the records are readily reproducible in that form or format.

(d) *Agreement to pay fees.* By making a FOIA request, the requester shall be considered to have agreed to pay all applicable fees up to $25, unless a fee waiver is granted. IPS will confirm this agreement in an acknowledgement letter. When making a request, the requester may specify a willingness to pay a greater or lesser amount. If the Department determines that costs and fees will exceed the amount agreed to by the requester, the Department shall inform the requester of estimated fees and process up to the amount of the original agreement, unless a new agreement is made.

(e) *Receipt of request.* The Department is in receipt of a request when it reaches IPS, OIG, or PPT, depending on which office is the intended recipient. At that time, the Department shall send an acknowledgement letter to the requester that identifies the date of receipt of the request in the proper component (IPS, OIG, or PPT), and the case tracking number. The Department (IPS, OIG, or PPT) has 20 working days in which to determine whether to comply with a perfected request. Regardless of which of the three offices authorized to receive

FOIA requests receives the request (whether IPS, OIG, or PPT), the Department shall have no more than 10 working days to direct a request to the appropriate office (whether IPS, OIG, or PPT), at which time the 20-day limit for responding to the request will commence. The 20-day period shall not be tolled by the Department except:

(1) The Department may make one request to the requester for clarifying information and toll the 20-day period while waiting for the requester's response; or

(2) If necessary to clarify with the requester issues regarding fees. In either case, the Department's receipt of the information from the requester ends the tolling period.

(f) *Expedited processing.* Requests shall receive expedited processing when a requester demonstrates that a "compelling need" for the information exists. A "compelling need" is deemed to exist where the requester can demonstrate one of the following:

(1) Failure to obtain requested information on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual.

(2) The information is urgently needed by an individual primarily engaged in disseminating information in order to inform the public concerning actual or alleged Federal government activity. Requesters must demonstrate that their primary activity involves publishing or otherwise disseminating information to the public in general, not just to a particular segment or group.

(3) Failure to release the information would impair substantial due process rights or harm substantial humanitarian interests.

(4) A request for expedited processing may be made at the time of the initial request for records or at any later time. The request for expedited processing shall set forth with specificity the facts on which the request is based. A notice of the determination whether to grant expedited processing shall be provided to the requester within 10 calendar days of the date of the receipt of the request in the appropriate office (whether IPS, OIG, or PPT). A denial of a request for expedited processing may be appealed to the Director of IPS within 30 calendar days of the date of the Department's letter denying the request. A decision in writing on the appeal will be issued within 10 calendar days of the receipt of the appeal. See § 171.4 for contact information.

(g) *Time limits.* The statutory time limit for responding to a FOIA request or to an appeal from a denial of a FOIA request is 20 working days. Whenever the statutory time limit for processing a request cannot be met because of "unusual circumstances" as defined in the FOIA, and the Department extends the time limit on that basis, the Department shall, before expiration of the 20-day period to respond, notify the requester in writing of the unusual circumstances involved and of the date by which processing of the request can be expected to be completed. See § 171.11(b)(4). Where the extension exceeds 10 working days, the Department shall, as described by the FOIA, provide the requester with an opportunity to modify the request or arrange an alternative time period for processing. The Department shall make available its designated FOIA contact and its FOIA Public Liaison for this purpose.

(h) *Multi-track processing.* The Department uses three processing tracks by distinguishing between simple and more complex requests based on the amount of work and/or time needed to process the request. The Department also uses a processing track for requests in which the Department has granted expedited processing. The Department may provide requesters in a slower track an opportunity to limit the scope of their request in order to qualify for faster processing.

(i) *Tracking requests.* Requesters may contact IPS using the individualized tracking number provided to the requester in the acknowledgment letter, and the Department will provide, at a minimum, information indicating the date on which the agency received the request and an estimated date for completion.

(j) *Cut-off date.* In determining which records are responsive to a request, the Department ordinarily will include only records in its possession as of the date of initiation of the search for responsive records, unless the requester has specified an earlier cut-off date.

(k) *Electronic records.* Information maintained in electronic form shall be searched and compiled in response to a request unless such search and compilation would significantly interfere with the operation of the Department's automated information systems.

(l) *Segregation of records.* The Department will release any reasonably segregable portion of a record after redaction of the exempt portions. The amount of information redacted and the exemption under which the redaction is made shall be indicated on the released portion of the record unless including that indication would harm an interest protected by the exemption. If technically feasible, the amount of information redacted and the exemption under which the redaction is made shall be indicated at the place in the record where the redaction was made.

(m) *Referrals and consultations.* (1) If the Department determines that records retrieved as responsive to the request were created by another agency, it ordinarily will refer the records to the originating agency for direct response to the requester. If the Department determines that Department records retrieved as responsive to the request are of interest to another agency or Federal government office, it may consult with the other agency or office before responding to the request.

(2) Whenever the Department refers any part of the responsibility for responding to a request to another agency, it shall document the referral, maintain a copy of the record that it refers, and notify the requester of the referral.

(3) Agreements regarding consultations and referrals. The Department may make agreements with other agencies to eliminate the need for consultations or referrals for particular types of records.

(4) The Department will make efforts to handle referrals and consultations according to the date that the referring agency initially received the FOIA request.

(5) The standard referral procedure is not appropriate where disclosure of the identity of the agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. In such instances, the Department will coordinate with the originating agency to seek its views on the disclosability of the record(s).

(n) *Requests for information about individuals to be processed under the FOIA*—(1) *First-party requests.* A first-party request is one that seeks access to information pertaining to the person making the request.

(2) *Verification of personal identity.* To protect the personal information found in its files, the Department recommends that first-party requesters provide the following information so that the Department can ensure that records are disclosed only to the proper persons: the requester's full name, current address, citizenship or legal permanent resident alien status, and date and place of birth (city, state, and country). A first-party request should be signed, and the requester's signature should be either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746 as a substitute for notarization.

(3) *Third-party requests.* A third-party request is one that seeks access to information pertaining to a third party (*i.e.,* an individual other than the person submitting the request). A third-party requester who is the legal representative of another person covered under the PA, and submits all requirements under subpart C of this part, will be treated as a first-party requester.

(i) A third-party requester may receive greater access to requested information by submitting information about the subject of the request that is set forth in paragraph (n)(1) of this section, and providing proof that that third party is deceased or the third party's authorization to the Department to release information about him- or herself to the requester. The third-party authorization: should take one of the following forms:

(ii) A signed and notarized authorization by the third party; or

(iii) A declaration by the third party made in compliance with the requirements set forth in 28 U.S.C. 1746 authorizing disclosure pertaining to the third party to the requester. The third-party authorization or declaration should be dated within six months of the date of the request. In addition, the Department's Certification of Identity form, DS–4240, can be used to provide authorization from a third party.

(iv) Please note that if a requester is seeking information about a third party and the information is located in a PA system of records, the requester should review subpart C of this part. By providing verification of identity and authorization under that subpart, the third party is treated as a first party for processing purposes. Without providing the required information listed in that subpart, the request will still be processed under the FOIA procedures in subpart B of this part.

(4) *Requests for visa information.* According to the Immigration and Nationality Act, 222(f) (8 U.S.C. 1202(f)), the records of the Department of State and of diplomatic and consular offices of the United States pertaining to the issuance or refusal of visas or permits to enter the United States shall be considered confidential and shall be used only for the formulation, amendment, administration, or enforcement of the immigration, nationality, and other laws of the United States. Other information found in the visa file, such as information submitted as part of the application and information not falling within section 222(f) or another FOIA exemption may be provided. In order to provide more information to requesters seeking visa records, the following information should be provided with the FOIA request for both the petitioner and the beneficiary: full name, as well as any aliases used; current address; date and place of birth (including city, state, and country); the type of visa (immigrant or non-immigrant); the country and Foreign Service post where the visa application was made; when the visa application was made; and whether the visa application was granted or denied; and if denied, on what grounds. Providing additional information regarding the records sought will assist the Department in properly identifying the responsive records and in processing the request. In order to gain maximum access to any visa records that exist, attorneys or other legal representatives requesting visa information on behalf of a represented individual should submit a statement signed by both the petitioner and the beneficiary authorizing release of the requested visa information to the representative. Alternatively, the Department's form, DS–4240, may be used to certify the identity of the requester and to provide authorization from the petitioner and the beneficiary to release the requested information to the legal representative. Forms created by other Federal agencies will not be accepted.

(5) *Requests for passport records.* All passport records requests must meet the requirements found in § 171.22(d). If the PA requirements are not met, the requests will be processed under this subpart and access may be limited.

§ 171.12 Business information.

(a) *Definitions.* The following definitions apply for purposes of this section:

(1) Business information means commercial or financial or proprietary intellectual information obtained by the Department from a submitter that may be exempt from disclosure as privileged or confidential under Exemption 4 of the FOIA.

(2) Submitter means any person or entity from which the Department obtains business information, directly or indirectly. The term includes corporations, partnerships, and sole proprietorships; state, local, and tribal governments; foreign governments, NGOs and educational institutions.

(b) *Designation of business information.* A submitter of information must use good-faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, any portions of its submission that it considers exempt from disclosure under FOIA Exemption 4. These designations will expire ten years after the date of the submission unless the submitter requests, and provides justification for, a longer designation period.

(c) *Notice to submitters.* The Department shall provide a submitter with prompt written notice of a FOIA request that seeks its business information, or of an administrative appeal of a denial of such a request, whenever required under paragraph (d) of this section, except as provided in paragraph (e) of this section, in order to give the submitter an opportunity to object to disclosure of any specified portion of that information under paragraph (f) of this section. The notice shall either describe the information requested or include copies of the requested records or record portions containing the business information.

(d) *When notice is required.* Notice shall be given to a submitter whenever:

(1) The information has been designated in good faith by the submitter as information considered exempt from disclosure under Exemption 4; or

(2) The Department has reason to believe that the information may be exempt from disclosure under Exemption 4, but has not yet determined whether the information is protected from disclosure under that exemption or any other applicable exemption.

(e) *When notice is not required.* The notice requirements of paragraphs (c) and (d) of this section shall not apply if:

(1) The Department determines that the information is exempt from disclosure;

(2) The information lawfully has been published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12600; or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous, except that, in such a case, the Department shall, within a reasonable time prior to a specified disclosure date, give the submitter written notice of any final decision to disclose the information.

(f) *Opportunity to object to disclosure.* The Department will allow a submitter a reasonable time to respond to the notice described in paragraph (c) of this section and will specify that time period in the notice. If a submitter has any objections to disclosure, it should provide the component a detailed written statement that specifies all grounds for withholding the particular information under any exemption of the FOIA. In order to rely on Exemption 4 as basis for nondisclosure, the submitter must explain why the information constitutes a trade secret or commercial or financial information that is privileged or confidential. In the event that a submitter fails to respond to the notice within the time specified in it, the submitter will be considered to have no objection to disclosure of the information. Information provided by a submitter under this paragraph may itself be subject to disclosure under the FOIA.

(g) *Notice of intent to disclose.* The Department shall consider a submitter's objections and specific grounds for nondisclosure in deciding whether to disclose business information. Whenever the Department decides to disclose business information over the objection of a submitter, it shall give the submitter written notice, which shall include:

(1) A statement of the reason(s) why each of the submitter's disclosure objections was not sustained;

(2) A description of the business information to be disclosed; and

(3) A specified disclosure date, which shall be a reasonable time subsequent to the notice.

(h) *Notice of lawsuit.* Whenever a requester files a lawsuit seeking to compel the disclosure of business information, the Department shall promptly notify the submitter.

(i) *Notice to requester.* Whenever the Department provides a submitter with notice and an opportunity to object to disclosure under paragraph (f) of this section, the Department shall also notify the requester. Whenever the Department notifies a submitter of its intent to disclose requested business information under paragraph (g) of this section, the Department shall also notify the requester. Whenever a submitter files a lawsuit seeking to prevent the disclosure of business information, the Department shall notify the requester.

§ 171.13 Appeal of denial of request for records.

(a) Any denial, in whole or in part, of a request for Department records under the FOIA may be administratively appealed to the Appeals Review Panel of the Department. This appeal right includes the right to appeal the determination that no records responsive to the request exist in Department files. Appeals must be postmarked within 60 calendar days of the date of the Department's denial letter and sent to: Appeals Officer, Appeals Review Panel, Office of Information Programs and Services, at the address set forth in § 171.4, or faxed to (202) 261–8571. The time limit for a response to an appeal is 20 working days, which may be extended in unusual circumstances, as defined in § 171.11(b). The time limit begins to run on the day the appeal is received by IPS. Appeals from denials of requests for expedited processing and for a fee reduction or waiver must be postmarked within 30 calendar days of the date of the Department's denial letter. See §§ 171.11(f)(4) (expedited processing appeals) and 171.16(e) (fee reduction/waiver appeals) of this subpart. See also § 171.4 for address information.

(b) Requesters may decide to litigate a request that is in the appeal stage. Once a summons and complaint is received by the Department in connection with a particular request, the Department will administratively close any open appeal regarding such request.

(c) Requesters should submit an administrative appeal, to IPS at the above address, of any denial, in whole or in part, of a request for access to FSGB records under the FOIA. IPS will assign a tracking number to the appeal and forward it to the FSGB, which is an independent body, for adjudication.

(d) *Decisions on appeals.* A decision on an appeal must be made in writing. A decision that upholds the Department's determination will contain a statement that identifies the reasons for the affirmance, including any FOIA and Privacy Act exemptions applied. The decision will provide the requester with notification of the statutory right to file a lawsuit and will inform the requester of the mediation services offered by the Office of Government Information Services of the National Archives and Records Administration (OGIS) as a non-exclusive alternative to litigation. If the Department's decision is remanded or modified on appeal, the requester will be notified of that determination in writing. The Department will thereafter further process the request in accordance with that appeal determination and respond directly to the requester. When the Department of State engages in the mediation services offered by OGIS, it will work in good faith as a partner to the mediation process in an attempt to resolve the dispute. The Department reserves its right to decide on a case-by-case basis whether to enter into formal mediation offered by OGIS.

§ 171.14 Fees to be charged.

(a) *In general.* The Department shall charge fees that recoup the full allowable direct costs it incurs in processing a FOIA request in accordance with the provisions of this part and with the OMB Guidelines. It shall use the most efficient and least costly methods to comply with requests for records made under the FOIA. The Department will not charge fees to any requester, including commercial use requesters, if the cost of collecting a fee would be equal to or greater than $25.00. The Department shall attempt to notify the requester if fees are estimated to exceed $25.00. Such notification shall include a breakdown of the fees for search, review, or duplication, unless the requester has expressed a willingness to pay fees as high as those anticipated.

(b) *Definitions.* The following definitions apply for purposes of this section:

(1) Direct costs are those costs the Department incurs in searching for, duplicating, and, in the case of commercial use requests, reviewing records in response to a FOIA request. The term does not include overhead expenses.

(2) Search costs are those costs the Department incurs in looking for, identifying, and retrieving material, in paper or electronic form, that is potentially responsive to a request. The Department shall attempt to ensure that searching for material is done in the most efficient and least expensive manner so as to minimize costs for both the Department and the requester. The Department may charge for time spent searching even if it does not locate any responsive record, or if it withholds the record(s) located as entirely exempt from disclosure. Further information on current search fees is available by visiting the FOIA home page at *www.foia.state.gov* and reviewing the Information Access Guide.

(3) Duplication costs are those costs the Department incurs in reproducing a requested record in a form appropriate for release in response to a FOIA request.

(4) Review costs are those costs the Department incurs in examining a record to determine whether and to what extent the record is responsive to a FOIA request and the extent to which it may be disclosed to the requester, including the page-by-page or line-by-line review of material within records. It does not include the costs of resolving general legal or policy issues that may be raised by a request.

(5) *Categories of requesters.* "Requester fee category" means one of the categories in which a requester will be placed for the purpose of determining whether the requester will be charged fees for search, review, and duplication. "Fee waiver" (see § 171.16)

means the waiver or reduction of processing fees that may be granted if the requester can demonstrate that certain statutory standards are satisfied. There are three categories of requesters: commercial use requesters, distinct subcategories of non-commercial requesters (educational and non-commercial scientific institutions, representatives of the news media), and all other requesters.

(i) A commercial use requester is a person or entity who seeks information for a use or purpose that furthers the commercial, trade, or profit interest of the requester or the person on whose behalf the request is made. In determining whether a requester belongs within this category, the Department will look at the way in which the requester intends to use the information requested. Commercial use requesters will be charged for search time, review time, and duplication in connection with processing their requests.

(ii) *Distinct subcategories of non-commercial requesters.* (A) An educational institution requester is a person or entity who submits a request under the authority of a school that operates a program of scholarly research. A requester in this category must show that the records are not sought for a commercial use and are not intended to promote any particular product or industry, but rather are sought to further scholarly research of the institution. A signed letter from the chairperson on an institution's letterhead is presumed to be from an educational institution. A student seeking inclusion in this subcategory who makes a request in furtherance of the completion of a course of instruction is carrying out an individual research goal and does not qualify as an educational institution requester. See a summary of the OMB Fee Guidelines at: *https://www.justice.gov/oip/foia-guide-2004-edition-fees-and-fee-waivers.* Educational institution requesters will not be charged for search and review time, and the first 100 pages of duplication will be provided free of charge.

(1) Example 1. A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

(2) Example 2. A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

(B) A non-commercial scientific institution requester is a person or entity that submits a request on behalf of an institution that is not operated on a "commercial" basis and that is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry. Non-commercial scientific institution requesters will not be charged for search and review time, and the first 100 pages of duplication will be provided free of charge.

(C) A representative of the news media is any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. The term news means information that is about current events or that would be of current interest to the public. News media include television or radio stations broadcasting to the public at large and publishers of periodicals (but only in those instances when they can qualify as disseminators of "news") who make their products available to the general public. "Freelance" journalists shall be regarded as working for a news media entity if they can demonstrate a solid basis for expecting publication through that entity, such as by a contract or past publication record. These examples are not all-inclusive. A representative of the news media will not be charged for search and review time, and the first 100 pages of duplication will be provided free of charge.

(iii) All other requesters are persons or entities that do not fall into the requester categories defined above. All other requesters will be provided the first two hours of search time and the first 100 pages of duplication free of charge, and will not be charged for review time.

(c) *Searches for responsive records.* The Department charges the estimated direct cost of each search based on the average current salary rates of the categories of personnel doing the searches. Updated search and review fees are available at *www.foia.state.gov*

(d) *Manual (paper) and computer searches.* For both manual and computer searches, the Department shall charge the estimated direct cost of each search based on the average current salary rates of the categories of personnel doing the searches.

(e) *Review of records.* Only requesters who are seeking records for commercial use may be charged for time spent reviewing records to determine whether they are responsive, and if so, releasable. Charges may be assessed for the initial review only, *i.e.,* the review undertaken the first time the Department analyzes the applicability of a specific exemption to a particular record or portion of a record

(f) *Duplication of records.* Paper copies of records shall be duplicated at a rate of $0.15 per page. Other charges may apply depending on the type of production required. Where paper documents must be scanned in order to comply with a requester's preference to receive the records in an electronic format, the requester shall pay the direct costs associated with scanning those materials. For other forms of duplication, the Department shall charge the direct costs.

(g) *Other charges.* The Department shall recover the full costs of providing services such as those below:

(1) Sending records by special methods such as express mail, overnight courier, etc.

(2) Providing records to a requester in a special format.

(3) Providing duplicate copies of records already produced to the same requester in response to the same request.

(h) *Payment.* Fees shall be paid by either personal check or bank draft drawn on a bank in the United States, or a postal money order. Remittances shall be made payable to the order of the Treasury of the United States and mailed to the Office of Information Programs and Services, U.S. Department of State, State Annex 2 (SA–2), 515 22nd Street NW., Washington, DC, 20522–8100. A receipt for fees paid will be given upon request.

(i) *When certain fees are not charged.* The Department shall not charge search fees (or in the case of educational and non-commercial scientific institutions or representatives of the news media, duplication fees) when the Department fails to comply with any time limit under 5 U.S.C. 552(a)(6), unless unusual circumstances (see § 171.11(b)) or exceptional circumstances exist. Exceptional circumstances cannot include a delay that results from a predictable agency workload of requests unless the agency demonstrates reasonable progress in reducing its backlog of pending requests. See 5 U.S.C. 552(a)(6)(C). Apart from the stated provisions regarding waiver or reduction of fees, see § 171.16, the Department retains the administrative discretion to not assess fees if it is in the best interests of the government to do so.

§ 171.15 Miscellaneous fee provisions.

(a) *Charging interest.* The Department shall begin assessing interest charges on an unpaid bill starting on the 31st day following the day on which the bill was sent. The fact that a fee has been received by the Department within the thirty-day grace period, even if not processed, shall stay the accrual of interest. Interest will be at the rate prescribed in 31 U.S.C. 3717 and shall accrue from the date of the billing.

(b) *Charges for unsuccessful search or if records are withheld.* The Department may assess charges for time spent searching, even if it fails to locate the records or if the records located are determined to be exempt from disclosure.

(c) *Advance payment.* The Department may not require a requester to make an advance payment, *i.e.,* payment before work is commenced or continued on a request, unless:

(1) It estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250. In such a case, the Department shall notify the requester of the likely cost and obtain satisfactory assurance of full payment where the requester has a history of prompt payment of FOIA fees, or shall, in its discretion, require an advance payment of an amount up to the full estimated charges in the case of requesters with no history of payment; or

(2) A requester has previously failed to pay an assessed fee within 30 days of the date of its billing. In such a case, the Department shall require the requester to pay the full amount previously owed plus any applicable interest and to make an advance payment of the full amount of the estimated fee before the Department begins to process a new or pending request from that requester.

(3) If a requester has failed to pay a fee properly charged by another U.S. government agency in a FOIA case, the Department may require proof that such fee has been paid before processing a new or pending request from that requester.

(4) When the Department acts under paragraph (c)(1) or (2) of this section, the administrative time limits prescribed in the FOIA, 5 U.S.C. 552(a)(6) (*i.e.,* 20 working days from receipt of initial requests and 20 working days from receipt of appeals, plus permissible extensions of these time limits), will begin only after the Department has received fee payments described in paragraphs (c)(1) and (2) of this section.

(d) *Aggregating requests.* When the Department reasonably believes that a requester, or a group of requesters acting in concert, has submitted multiple requests involving related matters solely to avoid payment of fees, the Department may aggregate those requests for purposes of assessing processing fees.

(e) *Effect of the Debt Collection Act of 1982, as amended.* The Department shall comply with provisions of the Debt Collection Act, including disclosure to consumer reporting agencies and use of collection agencies, where appropriate, to effect repayment.

(f) *Itemization of charges.* The Department shall, where possible, provide the requester with a breakdown of fees charged indicating how much of the total charge is for search, review, and/or duplication for each specific request.

§ 171.16 Waiver or reduction of fees.

(a) Fees otherwise chargeable in connection with a request for disclosure of a record shall be waived or reduced where the requester seeks a waiver or reduction of fees and the Department determines, in its discretion, that disclosure is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(1) In deciding whether disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of operations or activities of the government, the Department shall consider all four of the following factors:

(i) The subject of the request must concern identifiable operations or activities of the Federal Government, with a connection that is direct and clear, not remote or attenuated.

(ii) Disclosure of the requested records must be meaningfully informative about government operations or activities in order to be "likely to contribute" to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public shall be considered. It shall be presumed that a representative of the news media will satisfy this consideration.

(iv) The public's understanding of the subject in question must be enhanced by the disclosure to a significant extent.

(2) In order to determine whether disclosure of the information is not primarily in the commercial interest of the requester, the Department will consider the following factors:

(i) The existence and magnitude of a commercial interest, *i.e.,* whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so,

(ii) The primary interest in disclosure, *i.e.,* whether disclosure is primarily in the commercial interest of the requester.

(iii) Requests for purposes of writing a book, an article, or other publication will not be considered a commercial purpose.

(b) The Department may refuse to consider waiver or reduction of fees for requesters from whom unpaid fees remain owed to the Department for another FOIA request.

(c) Where only some of the records to be released satisfy the requirements for a waiver or reduction of fees, a waiver or reduction shall be granted for only those records.

(d) Requests for a waiver or reduction of fees should be made when the request is first submitted to the Department and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester shall be required to pay any costs incurred up to the date the fee waiver request was received.

(e) The Division Chief of the Requester Liaison Division in IPS will issue all initial decisions on whether to grant or deny requests for a fee waiver. A decision to refuse to waive or reduce fees may be appealed to the Director of IPS within 30 calendar days of the date of the Department's refusal letter. See § 171.4 for address information. A decision in writing on the appeal shall be issued within 20 working days of the receipt of the appeal.

§ 171.17 Resolving disputes.

The Office of Government Information Services (OGIS) in the National Archives and Records Administration is charged with offering mediation services to resolve disputes between persons making FOIA requests and Federal agencies as a non-exclusive alternative to litigation. Additionally, the FOIA directs the Department's FOIA Public Liaison to assist in the resolution of disputes. The Department will inform requesters in its agency appeal response letter of services offered by OGIS and the FOIA Public Liaison. Requesters may reach the Department's FOIA Public Liaison at Office of Information Programs and Services, A/GIS/IPS/PP/LA, U.S. Department of State, Washington, DC 20522–8100, or at (202) 261–8484. Requesters may contact OGIS at Office of Government Information Services (OGIS), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001; at *ogis@nara.gov;* and at (202) 741–5770, or toll-free at (877) 684–6448.

§ 171.18 Preservation of records

The Department shall preserve all correspondence pertaining to the requests that it receives under this subpart, as well as copies of all requested records, until disposition or destruction is authorized pursuant to title 44 of the United States Code or the General Records Schedule 14 of the National Archives and Records Administration. Records shall not be disposed of or destroyed while they are the subject of a pending request, appeal, or lawsuit under the FOIA.

Subpart C—Privacy Act Provisions

§ 171.20 Purpose and scope.

This subpart contains the rules that the Department follows under the Privacy Act of 1974 (PA), 5 U.S.C. 552a, as amended. These rules should be read together with the text of the statute, which provides additional information about records maintained on individuals. The rules in this subpart apply to all records in systems of records maintained by the Department that are retrieved by an individual's name or personal identifier. They describe the procedures by which individuals may request access to records about themselves, request amendment or correction of those records, and request an accounting of disclosures of those records by the Department. If any records retrieved pursuant to an access request under the PA are found to be exempt from access under that Act, they will be processed for possible disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended. No fees shall be charged for access to or amendment of PA records.

§ 171.21 Definitions.

As used in this subpart, the following definitions shall apply:

(a) Individual means a citizen or a legal permanent resident alien (LPR) of the United States.

(b) Maintain includes maintain, collect, use, or disseminate.

(c) Record means any item, collection, or grouping of information about an individual that is maintained by the Department and that contains the individual's name or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or photograph.

(d) System of records means a group of any records under the control of the Department from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to an individual.

§ 171.22 Request for access to records.

(a) *In general.* Requests for access to records under the PA must be made in writing and mailed to the Office of Information Programs and Service, the Office of Passport Services, or the Office of Inspector General at the addresses given in § 171.4. The Director of the Office of Information Programs and Services (IPS) is responsible for acting on all PA requests for Department records except for requests received directly by the Office of Inspector General, which processes its own requests for information, and the Office of Passport Services within the Bureau of Consular Affairs which receives directly and processes its own PA requests for information as described in PA System of Record Notice 26. Once received by IPS, all processing of PA requests coming under the jurisdiction of the Bureau of Consular Affairs/Visa Services Office and Overseas Citizens Services, the Bureau of Diplomatic Security, the Bureau of Human Resources, the Office of Medical Services, and the Foreign Service Grievance Board (FSGB) are handled by those bureaus or offices instead of IPS.

(b) *Description of records sought.* Requests for access should describe the requested record(s) in sufficient detail to permit identification of the record(s). At a minimum, requests should include the individual's full name (including maiden name, if appropriate) and any other names used, current complete mailing address, and date and place of birth (city, state and country). Helpful data includes the approximate time period of the record and the circumstances that give the individual reason to believe that the Department maintains a record under the individual's name or personal identifier, and, if known, the system of records in which the record is maintained. In certain instances, it may be necessary for the Department to request additional information from the requester, either to ensure a full search, or to ensure that a record retrieved does in fact pertain to the individual.

(c) *Verification of personal identity.* The Department will require reasonable identification of individuals requesting records about themselves under the PA's access provisions to ensure that records are only accessed by the proper persons. Requesters must state their full name, current address, citizenship or legal permanent resident alien status, and date and place of birth (city, state, and country). The request must be signed, and the requester's signature must be either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746. If the requester seeks records under another name the requester has used, a statement, under penalty of perjury, that the requester has also used the other name must be included. Requesters seeking access to copies of the Passport Office's passport records must meet the requirements in paragraph (d) of this section.

(d) *Special requirements for passport records.* Given the sensitive nature of passport records and their use, requesters seeking access to copies of the Passport Office's passport records under the PA must submit a letter that is either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746, which includes the full name at birth and any subsequent name changes of the individual whose records are being requested (if submitting the request on behalf of a minor, provide the representative's full name as well); the date and place of birth of the individual whose records are being requested; the requester's current mailing address; and, if available, daytime telephone number and email address; the date or estimated date the passport(s) was issued; the passport number of the person whose records are being sought, if known; and any other information that will help to locate the records. The requester must also include a clear copy of both sides of the requester's valid Government-issued photo identification, *e.g.*, a driver's license.

(e) *Authorized third party access.* The Department shall process all properly authorized third party requests, as described in this section, under the PA. In the absence of proper authorization from the individual to whom the records pertain, the Department will process third party requests under the FOIA. The Department's form, DS–4240, may be used to certify identity and provide third party authorization.

(1) *Parents and guardians of minor children.* Upon presentation of acceptable documentation of the parental or guardian relationship, a

parent or guardian of a U.S. citizen or LPR minor (an unmarried person under the age of 18) may, on behalf of the minor, request records under the PA pertaining to the minor. In any case, U.S. citizen or LPR minors may request such records on their own behalf.

(2) *Guardians.* A guardian of an individual who has been declared by a court to be incompetent may act for and on behalf of the incompetent individual upon presentation of appropriate documentation of the guardian relationship.

(3) *Authorized representatives or designees.* When an individual wishes to authorize another person or persons access to his or her records, the individual may submit, in addition to the identity verification information described in paragraph (c) or paragraph (d) of this section if the request is for passport records, a signed statement from the individual to whom the records pertain, either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746, giving the Department authorization to release records about the individual to the third party. The designated third party must submit identity verification information described in paragraph c. Third party requesters seeking access to copies of the Passport Office's records must submit a clear copy of both sides of a valid Government-issued photo identification (*e.g.,* a driver's license) in addition to the other information described above.

(f) *Referrals and consultations.* If the Department determines that records retrieved as responsive to the request were created by another agency, it ordinarily will refer the records to the originating agency for direct response to the requester. If the Department determines that Department records retrieved as responsive to the request are of interest to another agency, it may consult with the other agency before responding to the request. The Department may make agreements with other agencies to eliminate the need for consultations or referrals for particular types of records.

(g) *Records relating to civil actions.* Nothing in this subpart entitles an individual to access to any information compiled in reasonable anticipation of a civil action or proceeding.

(h) *Time limits.* The Department will acknowledge the request promptly and furnish the requested information as soon as possible thereafter.

§ 171.23 Request to amend or correct records.

(a) An individual has the right to request that the Department amend a record pertaining to the individual that the individual believes is not accurate, relevant, timely, or complete.

(b) Requests to amend records must be in writing and mailed or delivered to the Office of Information Programs and Services at the address given in § 171.4, with ATTENTION: PRIVACY ACT AMENDMENT REQUEST written on the envelope. IPS will coordinate the review of the request with the appropriate offices of the Department. The Department will require verification of personal identity as provided in section 171.22(c) before it will initiate action to amend a record. Amendment requests should contain, at a minimum, identifying information needed to locate the record in question, a description of the specific correction requested, and an explanation of why the existing record is not accurate, relevant, timely, or complete. The request must be signed, and the requester's signature must be either notarized or made under penalty of perjury pursuant to 28 U.S.C. 1746. The requester should submit as much pertinent documentation, other information, and explanation as possible to support the request for amendment.

(c) All requests for amendments to records shall be acknowledged within 10 working days.

(d) In reviewing a record in response to a request to amend, the Department shall review the record to determine if it is accurate, relevant, timely, and complete.

(e) If the Department agrees with an individual's request to amend a record, it shall:

(1) Advise the individual in writing of its decision;

(2) Amend the record accordingly; and

(3) If an accounting of disclosure has been made, advise all previous recipients of the record of the amendment and its substance.

(f) If the Department denies an individual's request to amend a record, it shall advise the individual in writing of its decision and the reason for the refusal, and the procedures for the individual to request further review. See § 171.25.

§ 171.24 Request for an accounting of record disclosures.

(a) How made. Except where accountings of disclosures are not required to be kept, as set forth in paragraph (b) of this section, or where accountings of disclosures do not need to be provided to a requesting individual pursuant to 5 U.S.C. 552a(c)(3), an individual has a right to request an accounting of any disclosure that the Department has made to another person, organization, or agency of any record about an individual. This accounting shall contain the date, nature, and purpose of each disclosure as well as the name and address of the recipient of the disclosure. Any request for accounting should identify each particular record in question and may be made by writing directly to the Office of Information Programs and Services at the address given in § 171.4.

(b) Where accountings not required. The Department is not required to keep an accounting of disclosures in the case of:

(1) Disclosures made to employees within the Department who have a need for the record in the performance of their duties; and

(2) Disclosures required under the FOIA.

§ 171.25 Appeals from denials of PA amendment requests.

(a) If the Department denies a request for amendment of such records, the requester shall be informed of the reason for the denial and of the right to appeal the denial to the Appeals Review Panel. Any such appeal must be postmarked within 60 working days of the date of the Department's denial letter and sent to: Appeals Officer, Appeals Review Panel, Office of Information Programs and Services, at the address set forth in § 171.4.

(b) Appellants should submit an administrative appeal of any denial, in whole or in part, of a request for access to FSGB records under the PA to IPS at the above address. IPS will assign a tracking number to the appeal and forward it to the FSGB, which is an independent body, for adjudication.

(c) The Appeals Review Panel will decide appeals from denials of PA amendment requests within 30 business days, unless the Panel extends that period for good cause shown, from the date when it is received by the Panel.

(d) Appeals Review Panel Decisions will be made in writing, and appellants will receive notification of the decision. A reversal will result in reprocessing of the request in accordance with that decision. An affirmance will include a brief statement of the reason for the affirmance and will inform the appellant that the decision of the Panel represents the final decision of the Department and of the right to seek judicial review of the Panel's decision, when applicable.

(e) If the Panel's decision is that a record shall be amended in accordance with the appellant's request, the Chairman shall direct the office responsible for the record to amend the record, advise all previous recipients of the record of the amendment and its substance (if an accounting of previous disclosures has been made), and so advise the individual in writing.

(f) If the Panel's decision is that the amendment request is denied, in addition to the notification required by paragraph (d) of this section, the Chairman shall advise the appellant:

(1) Of the right to file a concise Statement of Disagreement stating the reasons for disagreement with the decision of the Department;

(2) Of the procedures for filing the Statement of Disagreement;

(3) That any Statement of Disagreement that is filed will be made available to anyone to whom the record is subsequently disclosed, together with, at the discretion of the Department, a brief statement by the Department summarizing its reasons for refusing to amend the record;

(4) That prior recipients of the disputed record will be provided a copy of any statement of disagreement, to the extent that an accounting of disclosures was maintained.

(g) If the appellant files a Statement of Disagreement under paragraph (f) of this section, the Department will clearly annotate the record so that the fact that the record is disputed is apparent to anyone who may subsequently access the record. When the disputed record is subsequently disclosed, the Department will note the dispute and provide a copy of the Statement of Disagreement. The Department may also include a brief summary of the reasons for not amending the record. Copies of the Department's statement shall be treated as part of the individual's record for granting access; however, it will not be subject to amendment by an individual under this part.

§ 171.26 Exemptions.

Systems of records maintained by the Department are authorized to be exempt from certain provisions of the PA under both general and specific exemptions set forth in the Act. In utilizing these exemptions, the Department is exempting only those portions of systems that are necessary for the proper functioning of the Department and that are consistent with the PA. Where compliance would not interfere with or adversely affect the law enforcement process, and/or where it may be appropriate to permit individuals to contest the accuracy of the information collected, the applicable exemption may be waived, either partially or totally, by the Department or the OIG, in the sole discretion of the Department or the OIG, as appropriate. Records exempt under 5 U.S.C. 552a(j) or (k) by the originator of the record remain exempt if subsequently incorporated into any Department system of records, provided the reason for the exemption remains valid and necessary.

(a) *General exemptions.* If exempt records are the subject of an access request, the Department will advise the requester of their existence and of the name and address of the source agency, unless that information is itself exempt from disclosure.

(1) Individuals may not have access to records maintained by the Department that are maintained or originated by the Central Intelligence Agency under 5 U.S.C. 552a(j)(1).

(2) In accordance with 5 U.S.C. 552a(j)(2), individuals may not have access to records maintained or originated by an agency or component thereof that performs as its principal function any activity pertaining to the enforcement of criminal laws, including police efforts to prevent, control, or reduce crime or to apprehend criminals, and the activities of prosecutors, courts, correctional, probation, pardon, or parole authorities, and which consists of:

(i) Information compiled for the purpose of identifying individual criminal offenders and alleged offenders and consisting only of identifying data and notations of arrests, the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status;

(ii) Information compiled for the purpose of a criminal investigation, including reports of informants and investigators, and associated with an identifiable individual; or

(iii) Reports identifiable to an individual compiled at any stage of the process of enforcement of the criminal laws from arrest or indictment through release from supervision. The reason for invoking these exemptions is to ensure effective criminal law enforcement processes. Records maintained by the Department in the following systems of records are exempt from all of the provisions of the PA except paragraphs (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (e)(7), (e)(9), (e)(10), and (e)(11), and (i), to the extent to which they meet the criteria of section (j)(2) of 5 U.S.C. 552a. The names of the systems correspond to those published in the **Federal Register** by the Department.

Office of Inspector General Investigation Management System. STATE–53.
Information Access Program Records. STATE–35.
Risk Analysis and Management. STATE–78.
Security Records. STATE–36.

(b) *Specific exemptions.* Portions of the following systems of records are exempt from 5 U.S.C. 552a(c)(3), (d), (e)(1), and (4), (G), (H), and (I), and (f). The names of the systems correspond to those published in the **Federal Register** by the Department.

(1) *Exempt under 5 U.S.C. 552a(k)(1).* Records contained within the following systems of records are exempt under this section to the extent that they are subject to the provisions of 5 U.S.C. 552(b)(1).

Board of Appellate Review Records. STATE–02.
Congressional Correspondence. STATE–43.
Congressional Travel Records. STATE–44.
Coordinator for the Combating of Terrorism Records. STATE–06.
External Research Records. STATE–10.
Extradition Records. STATE–11.
Family Advocacy Case Records. STATE–75.
Foreign Assistance Inspection Records. STATE–48.
Human Resources Records. STATE–31.
Information Access Programs Records. STATE–35.
Intelligence and Research Records. STATE–15.
International Organizations Records. STATE–17.
Law of the Sea Records. STATE–19.
Legal Case Management Records. STATE–21.
Munitions Control Records. STATE–42.
Overseas Citizens Services Records. STATE–05.
Passport Records. STATE–26.
Personality Cross Reference Index to the Secretariat Automated Data Index. STATE–28.
Personality Index to the Central Foreign Policy Records. STATE–29.
Personnel Payroll Records. STATE–30.
Office of Inspector General Investigation Management System. STATE–53.
Records of the Office of the Assistant Legal Adviser for International Claims and Investment Disputes. STATE–54.
Risk Analysis and Management Records. STATE–78.
Rover Records. STATE–41.
Records of Domestic Accounts Receivable. STATE–23.
Records of the Office of White House Liaison. STATE–34.
Refugee Records. STATE–59.
Security Records. STATE–36.
Visa Records. STATE–39.

(2) *Exempt under 5 U.S.C. 552a(k)(2).* Records contained within the following

systems of records are exempt under this section to the extent that they consist of investigatory material compiled for law enforcement purposes, subject to the limitations set forth in 5 U.S.C. 552a(k)(2).

Board of Appellate Review Records. STATE–02.

Coordinator for the Combating of Terrorism Records. STATE–06.

Extradition Records. STATE–11.

Family Advocacy Case Records. STATE–75

Foreign Assistance Inspection Records. STATE–48.

Garnishment of Wages Records. STATE–61.

Information Access Program Records. STATE–35.

Intelligence and Research Records. STATE–15.

Munitions Control Records. STATE–42.

Overseas Citizens Services Records. STATE–05.

Passport Records. STATE–26.

Personality Cross Reference Index to the Secretariat Automated Data Index. STATE–28.

Personality Index to the Central Foreign Policy Records. STATE–29.

Office of Inspector General Investigation Management System. STATE–53.

Risk Analysis and Management Records. STATE–78.

Security Records. STATE–36.

Visa Records. STATE–39.

(3) *Exempt under 5 U.S.C. 552a(k)(3).* Records contained within the following systems of records are exempt under this section to the extent that they are maintained in connection with providing protective services pursuant to 18 U.S.C. 3056.

Extradition Records. STATE–11.

Information Access Programs Records. STATE–35.

Intelligence and Research Records. STATE–15.

Overseas Citizens Services Records. STATE–05.

Passport Records. STATE–26.

Personality Cross-Reference Index to the Secretariat Automated Data Index. STATE–28.

Personality Index to the Central Foreign Policy Records. STATE–29.

Security Records. STATE–36.

Visa Records. STATE–39.

(4) *Exempt under 5 U.S.C. 552a(k)(4).* Records contained within the following systems of records are exempt under this section to the extent that they are required by statute to be maintained and are used solely as statistical records.

Foreign Service Institute Records. STATE–14.

Human Resources Records. STATE–31.

Information Access Programs Records. STATE–35.

Overseas Citizens Services Records, STATE–05

Personnel Payroll Records. STATE–30.

Security Records. STATE–36.

(5) *Exempt under 5 U.S.C. 552a(k)(5).* Records contained within the following systems of records are exempt under this section to the extent that they consist of investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information, but only to the extent that disclosure of such material would reveal the identity of a confidential informant.

Records Maintained by the Office of Civil Rights. STATE–09.

Foreign Assistance Inspection Records. STATE–48.

Foreign Service Grievance Board Records. STATE–13.

Human Resources Records. STATE–31.

Information Access Programs Records. STATE–35.

Legal Adviser Attorney Employment Application Records. STATE–20.

Overseas Citizens Services Records. STATE–25.

Personality Cross-Reference Index to the Secretariat Automated Data Index. STATE–28.

Office of Inspector General Investigation Management System. STATE–53.

Records of the Office of White House Liaison. STATE–34.

Risk Analysis and Management Records. STATE–78.

Rover Records. STATE–41.

Security Records. STATE–36.

Senior Personnel Appointments Records. STATE–47.

(6) *Exempt under 5 U.S.C. 552a(k)(6).* Records contained within the following systems of records are exempt under this section to the extent that they consist of testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service the disclosure of which would compromise the objectivity or fairness of the testing or examination process.

Foreign Service Institute Records. STATE–14.

Human Resources Records. STATE–31.

Information Access Programs Records. STATE–35.

Records Maintained by the Office of Civil Rights. STATE–09

Security Records. STATE–36.

(7) *Exempt under 5 U.S.C. 552a(k)(7).* Records contained within the following systems of records are exempt under this section to the extent that they consist of evaluation material used to determine potential for promotion in the armed services, but only to the extent that such disclosure would reveal the identity of a confidential informant.

Overseas Citizens Services Records. STATE–25.

Human Resources Records. STATE–31.

Information Access Programs Records. STATE–35.

Personality Cross-Reference Index to the Secretariat Automated Data Index. STATE–28.

Personality Index to the Central Foreign Policy Records. STATE–29.

Subpart D—Process To Request Public Financial Disclosure Reports

§ 171.30 Purpose and scope.

This subpart sets forth the process by which persons may request access to public financial disclosure reports filed with the Department in accordance with sections 101 and 103(l) of the Ethics in Government Act of 1978, 5 U.S.C. app. 101 and 103(l), as amended. The retention, public availability, and improper use of these reports are governed by 5 U.S.C. app. 105 and 5 CFR 2634.603.

§ 171.31 Requests.

Requests for access to public financial disclosure reports filed with the Department should be made by submitting a completed Office of Government Ethics request form, OGE Form 201, to *OGE201Request@state.gov* or the Office of the Assistant Legal Adviser for Ethics and Financial Disclosure, U.S. Department of State, 2201 C Street NW., Washington, DC 20520. The OGE Form 201 may be obtained by visiting *http://www.oge.gov* or writing to the address above.

Dated: March 30, 2016.

Joyce A. Barr,

Assistant Secretary for Administration, Department of State.

[FR Doc. 2016–07900 Filed 4–5–16; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 169

[167 A2100DD/AAKC001030/ A0A501010.999900]

RIN 1076–AF20

Rights-of-Way on Indian Land

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; guidance on applicability.

SUMMARY: The Bureau of Indian Affairs (BIA) published a final rule on November 19, 2015, governing rights-of-way on Indian land, which stated that procedural provisions of the final rule would apply (with certain exceptions) to rights-of-way granted or submitted to BIA prior to the effective date of the final rule. This document provides guidance on what provisions the Department considers to be "procedural provisions" that are applicable to rights-of-way granted or submitted prior to the effective date of the final rule.

DATES: This guidance is effective on April 6, 2016.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, Office of the Assistant Secretary—Indian Affairs, U.S. Department of the Interior (202) 273–4680; *elizabeth.appel@bia.gov.*

SUPPLEMENTARY INFORMATION: On November 19, 2015, BIA published a final rule addressing rights-of-way on Indian land and BIA land. *See* 80 FR 72492. In a document published December 21, 2015, BIA extended the effective date of the rule to March 21, 2016, in response to requests from Tribes and industry. *See* 80 FR 79258. BIA again extended the effective date of the final rule to April 21, 2016. *See* 81 FR 14976 (March 21, 2016).

In § 169.7(b), the final rule states that its procedural provisions apply to rights-of-way that were granted prior to the final rule's effective date (with certain exceptions). Likewise, in § 169.7(c)(2), the final rule states that if an application for a right-of-way was pending as of the effective date of the final rule, and the applicant chose not to withdraw and resubmit the application on or after the final rule's effective date, the procedural provisions of the final rule apply (with certain exceptions) once BIA issues the right-of-way grant. In either situation, if the procedural provisions of the final rule conflict with the explicit provisions of the right-of-way grant or statute authorizing the right-of-way document, then the provisions of the right-of-way grant or authorizing statute will apply. In short, if a right-of-way was granted prior to the effective date of the rule, or an application for a right-of-way was pending as of the effective date of the rule, only the procedural provisions of the final rule apply to those grants and the other provisions do not apply to those grants. If an existing right-of-way is amended, assigned, or mortgaged, on or after the effective date of the rule, the final rule's procedural provisions apply to that amendment, assignment, or mortgage. An "existing right-of-way" is a grant issued before the effective date of the final rule, or a grant for which the application was pending on the effective date of the final rule is issued after the effective date of the final rule.

This document provides guidance regarding which provisions BIA considers procedural (and thus applicable to all right-of-way grants, regardless of when issued, and applicable to all amendments, assignments, and mortgages of existing right-of-way grants, unless the procedural provision conflicts with the explicit provisions of the right-of-way grant or authorizing statute).

Procedural Provisions in Final Rights-of-Way on Indian Land Rule

Subpart A—Purpose, Definitions, General Provisions

- § 169.12 How does BIA provide notice to the parties to a right-of-way?
- § 169.13 May decisions under this part be appealed?

Subpart B—Service Line Agreements

- [No procedural provisions] **Note:** If you have a service line that is not in compliance with the older version of the regulations, you may be in trespass.

Subpart C—Obtaining a Right-of-Way

- § 169.107 Must I obtain tribal or individual Indian landowner consent for a right-of-way across Indian land? **Note:** This provision is procedural only with regard to the grant of an amendment, assignment, or mortgage of an existing right-of-way after the effective date of the final rule; otherwise, it is prospective.
- § 169.109 Whose consent do I need for a right-of-way when there is a life estate on the tract? **Note:** This provision is procedural only with regard to the grant of an amendment, assignment, or mortgage of an existing right-of-way after the effective date of the final rule; otherwise, it is prospective.
- § 169.119 Will BIA notify a grantee when a payment is due for a right-of-way?
- § 169.127 Is a new right-of-way grant required for a new use within or overlapping an existing right-of-way?
- § 169.129 What is required if the location described in the original application and grant differs from the construction location?

Subpart D—Duration, Renewals, Amendments, Assignments, Mortgages

- § 169.202 Under what circumstances will a grant of right-of-way be renewed?
- § 169.203 May a right-of-way be renewed multiple times?
- § 169.204 May a grantee amend a right-of-way?
- § 169.205 What is the approval process for an amendment of a right-of-way?
- § 169.206 How will BIA decide whether to approve an amendment of a right-of-way?
- § 169.207 May a grantee assign a right-of-way?
- § 169.208 What is the approval process for an assignment of a right-of-way?
- § 169.209 How will BIA decide whether to approve an assignment of a right-of-way?
- § 169.210 May a grantee mortgage a right-of-way?
- § 169.211 What is the approval process for a mortgage of a right-of-way?
- § 169.212 How will BIA decide whether to approve a mortgage of a right-of-way?

Subpart E—Effectiveness

- § 169.301 When will a right-of-way document be effective?
- § 169.302 Must a right-of-way be recorded?
- § 169.303 What happens if BIA denies a right-of-way document?
- § 169.304 What happens if BIA does not meet a deadline for issuing a decision on a right-of-way document?
- § 169.305 Will BIA require an appeal bond for an appeal of a decision on a right-of-way document?

Subpart F—Compliance and Enforcement

- § 169.402 Who may investigate compliance with a right-of-way?
- § 169.404 What will BIA do about a violation of a right-of-way grant?
- § 169.405 What will BIA do if the grantee does not cure a violation of a right-of-way grant on time?
- § 169.406 Will late payment charges, penalties, or special fees apply to delinquent payments due under a right-of-way grant?

- § 169.407 How will payment rights relating to a right-of-way grant be allocated?
- § 169.408 What is the process for cancelling a right-of-way for non-use or abandonment?
- § 169.409 When will a cancellation of a right-of-way grant be effective?
- § 169.410 What will BIA do if a grantee remains in possession after a right-of-way expires or is terminated or cancelled?
- § 169.411 Will BIA appeal bond regulations apply to cancellation decisions involving right-of-way grants?
- § 169.412 When will BIA issue a decision on an appeal from a right-of-way decision?
- § 169.415 How will BIA conduct compliance and enforcement when there is a life estate on the tract?

All other provisions of the final rule are general statements or apply prospectively only. A chart providing more information on each provision and how it applies can be viewed at: *http://www.bia.gov/WhoWeAre/AS-IA/ORM/RightsofWay/index.htm.*

Dated: March 29, 2016.

Lawrence S. Roberts,

Acting Assistant Secretary—Indian Affairs.

[FR Doc. 2016–07868 Filed 4–5–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 554

Burundi Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is issuing regulations to implement Executive Order 13712 of November 22, 2015 ("Blocking Property of Certain Persons Contributing to the Situation in Burundi"). OFAC intends to supplement this part 554 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

DATES: *Effective:* April 6, 2016.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs also is available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Background

On November 22, 2015, the President issued Executive Order 13712 (80 FR 73633, November 25, 2015) (E.O. 13712), invoking the authority of, *inter alia,* the International Emergency Economic Powers Act (50 U.S.C. 1701–1706). OFAC is issuing the Burundi Sanctions Regulations, 31 CFR part 554 (the "Regulations"), to implement E.O. 13712, pursuant to authorities delegated to the Secretary of the Treasury in E.O. 13712. A copy of E.O. 13712 appears in Appendix A to this part.

The Regulations are being published in abbreviated form at this time for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part 554 with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance, and additional general licenses and statements of licensing policy. The appendix to the Regulations will be removed when OFAC supplements this part with a more comprehensive set of regulations.

Public Participation

Because the Regulations involve a foreign affairs function, the provisions of Executive Order 12866 and the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act (5 U.S.C. 601–612) does not apply.

Paperwork Reduction Act

The collections of information related to the Regulations are contained in 31 CFR part 501 (the "Reporting, Procedures and Penalties Regulations"). Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), those collections of information have been approved by the Office of Management and Budget under control number 1505–0164. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

List of Subjects in 31 CFR Part 554

Administrative practice and procedure, Banking, Banks, Blocking of assets, Brokers, Burundi, Credit, Foreign Trade, Investments, Loans, Securities, Services.

For the reasons set forth in the preamble, the Department of the Treasury's Office of Foreign Assets Control adds part 554 to 31 CFR chapter V to read as follows:

PART 554—BURUNDI SANCTIONS REGULATIONS

Subpart A—Relation of This Part to Other Laws and Regulations

Sec.
554.101 Relation of this part to other laws and regulations.

Subpart B—Prohibitions

554.201 Prohibited transactions.
554.202 Effect of transfers violating the provisions of this part.
554.203 Holding of funds in interest-bearing accounts; investment and reinvestment.
554.204 Expenses of maintaining blocked property; liquidation of blocked property.

Subpart C—General Definitions

554.300 Applicability of definitions.
554.301 Blocked account; blocked property.
554.302 Effective date.
554.303 Entity.
554.304 Financial, material, or technological support.
554.305 Interest.
554.306 Licenses; general and specific.
554.307 OFAC.
554.308 Person.
554.309 Property; property interest.
554.310 Transfer.
554.311 United States.
554.312 United States person; U.S. person.
554.313 U.S. financial institution.

Subpart D—Interpretations

554.401 [Reserved]
554.402 Effect of amendment.
554.403 Termination and acquisition of an interest in blocked property.
554.404 Transactions ordinarily incident to a licensed transaction.
554.405 Setoffs prohibited.
554.406 Entities owned by one or more persons whose property and interests in property are blocked.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

554.501 General and specific licensing procedures.
554.502 [Reserved]
554.503 Exclusion from licenses.
554.504 Payments and transfers to blocked accounts in U.S. financial institutions.

554.505 Entries in certain accounts for normal service charges authorized.
554.506 Provision of certain legal services authorized.
554.507 Payments for legal services from funds originating outside the United States authorized.
554.508 Authorization of emergency medical services.

Subpart F and G —[Reserved]

Subpart H—Procedures

554.801 [Reserved]
554.802 Delegation by the Secretary of the Treasury.

Subpart I—Paperwork Reduction Act

554.901 Paperwork Reduction Act notice.

APPENDIX A TO PART 554—Executive Order 13712

Authority: 3 U.S.C. 301; 31 U.S.C. 321(b); 50 U.S.C. 1601–1651, 1701–1706; Pub. L. 101–410, 104 Stat. 890 (28 U.S.C. 2461 note); Pub. L. 110–96, 121 Stat. 1011 (50 U.S.C. 1705 note); E.O. 13712, 80 FR 73633, November 25, 2015.

Subpart A—Relation of This Part to Other Laws and Regulations

§ 554.101 Relation of this part to other laws and regulations.

This part is separate from, and independent of, the other parts of this chapter, with the exception of part 501 of this chapter, the recordkeeping and reporting requirements and license application and other procedures of which apply to this part. Actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. Differing foreign policy and national security circumstances may result in differing interpretations of similar language among the parts of this chapter. No license or authorization contained in or issued pursuant to those other parts authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to any other provision of law or regulation authorizes any transaction prohibited by this part. No license or authorization contained in or issued pursuant to this part relieves the involved parties from complying with any other applicable laws or regulations.

Note to § 554.101: This part has been published in abbreviated form for the purpose of providing immediate guidance to the public. OFAC intends to supplement this part with a more comprehensive set of regulations, which may include additional interpretive and definitional guidance and additional general licenses and statements of licensing policy.

Subpart B—Prohibitions

§ 554.201 Prohibited transactions.

All transactions prohibited pursuant to Executive Order 13712 of November 22, 2015, are also prohibited pursuant to this part.

Note 1 to § 554.201: The names of persons listed in or designated pursuant to Executive Order 13712, whose property and interests in property therefore are blocked pursuant to this section, are published in the **Federal Register** and incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) with the identifier "[BURUNDI]." The SDN List is accessible through the following page on OFAC's Web site: *www.treasury.gov/sdn.* Additional information pertaining to the SDN List can be found in Appendix A to this chapter. *See* § 554.406 concerning entities that may not be listed on the SDN List but whose property and interests in property are nevertheless blocked pursuant to this section.

Note 2 to § 554.201: The International Emergency Economic Powers Act (50 U.S.C. 1701–1706), in Section 203 (50 U.S.C. 1702), authorizes the blocking of property and interests in property of a person during the pendency of an investigation. The names of persons whose property and interests in property are blocked pending investigation pursuant to this section also are published in the **Federal Register** and incorporated into the SDN List with the identifier "[BPI–BURUNDI]".

Note 3 to § 554.201: Sections 501.806 and 501.807 of this chapter describe the procedures to be followed by persons seeking, respectively, the unblocking of funds that they believe were blocked due to mistaken identity, or administrative reconsideration of their status as persons whose property and interests in property are blocked pursuant to this section.

§ 554.202 Effect of transfers violating the provisions of this part.

(a) Any transfer after the effective date that is in violation of any provision of this part or of any regulation, order, directive, ruling, instruction, or license issued pursuant to this part, and that involves any property or interest in property blocked pursuant to § 554.201, is null and void and shall not be the basis for the assertion or recognition of any interest in or right, remedy, power, or privilege with respect to such property or property interest.

(b) No transfer before the effective date shall be the basis for the assertion or recognition of any right, remedy, power, or privilege with respect to, or any interest in, any property or interest in property blocked pursuant to § 554.201, unless the person who holds or maintains such property, prior to that date, had written notice of the transfer or by any written evidence had recognized such transfer.

(c) Unless otherwise provided, a license or other authorization issued by OFAC before, during, or after a transfer shall validate such transfer or make it enforceable to the same extent that it would be valid or enforceable but for the provisions of this part and any regulation, order, directive, ruling, instruction, or license issued pursuant to this part.

(d) Transfers of property that otherwise would be null and void or unenforceable by virtue of the provisions of this section shall not be deemed to be null and void or unenforceable as to any person with whom such property is or was held or maintained (and as to such person only) in cases in which such person is able to establish to the satisfaction of OFAC each of the following:

(1) Such transfer did not represent a willful violation of the provisions of this part by the person with whom such property is or was held or maintained (and as to such person only);

(2) The person with whom such property is or was held or maintained did not have reasonable cause to know or suspect, in view of all the facts and circumstances known or available to such person, that such transfer required a license or authorization issued pursuant to this part and was not so licensed or authorized, or, if a license or authorization did purport to cover the transfer, that such license or authorization had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained; and

(3) The person with whom such property is or was held or maintained filed with OFAC a report setting forth in full the circumstances relating to such transfer promptly upon discovery that:

(i) Such transfer was in violation of the provisions of this part or any regulation, ruling, instruction, license, or other directive or authorization issued pursuant to this part;

(ii) Such transfer was not licensed or authorized by OFAC; or

(iii) If a license did purport to cover the transfer, such license had been obtained by misrepresentation of a third party or withholding of material facts or was otherwise fraudulently obtained.

Note to paragraph (d): The filing of a report in accordance with the provisions of paragraph (d)(3) of this section shall not be deemed evidence that the terms of paragraphs (d)(1) and (2) of this section have been satisfied.

(e) Unless licensed pursuant to this part, any attachment, judgment, decree, lien, execution, garnishment, or other judicial process is null and void with respect to any property and interests in property blocked pursuant to § 554.201.

§ 554.203 Holding of funds in interest-bearing accounts; investment and reinvestment.

(a) Except as provided in paragraphs (e) or (f) of this section, or as otherwise directed or authorized by OFAC, any U.S. person holding funds, such as currency, bank deposits, or liquidated financial obligations, subject to § 554.201 shall hold or place such funds in a blocked interest-bearing account located in the United States.

(b)(1) For purposes of this section, the term *blocked interest-bearing account* means a blocked account:

(i) In a federally-insured U.S. bank, thrift institution, or credit union, provided the funds are earning interest at rates that are commercially reasonable; or

(ii) With a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*), provided the funds are invested in a money market fund or in U.S. Treasury bills.

(2) Funds held or placed in a blocked account pursuant to paragraph (a) of this section may not be invested in instruments the maturity of which exceeds 180 days.

(c) For purposes of this section, a rate is commercially reasonable if it is the rate currently offered to other depositors on deposits or instruments of comparable size and maturity.

(d) For purposes of this section, if interest is credited to a separate blocked account or subaccount, the name of the account party on each account must be the same.

(e) Blocked funds held in instruments the maturity of which exceeds 180 days at the time the funds become subject to § 554.201 may continue to be held until maturity in the original instrument, provided any interest, earnings, or other proceeds derived therefrom are paid into a blocked interest-bearing account in accordance with paragraphs (a) or (f) of this section.

(f) Blocked funds held in accounts or instruments outside the United States at the time the funds become subject to § 554.201 may continue to be held in the same type of accounts or instruments, provided the funds earn interest at rates that are commercially reasonable.

(g) This section does not create an affirmative obligation for the holder of blocked tangible property, such as chattels or real estate, or of other blocked property, such as debt or equity securities, to sell or liquidate such property. However, OFAC may issue licenses permitting or directing such sales or liquidation in appropriate cases.

(h) Funds subject to this section may not be held, invested, or reinvested in a manner that provides immediate financial or economic benefit or access to any person whose property and interests in property are blocked pursuant to § 554.201, nor may their holder cooperate in or facilitate the pledging or other attempted use as collateral of blocked funds or other assets.

§ 554.204 Expenses of maintaining blocked property; liquidation of blocked property.

(a) Except as otherwise authorized, and notwithstanding the existence of any rights or obligations conferred or imposed by any international agreement or contract entered into or any license or permit granted prior to the effective date, all expenses incident to the maintenance of physical property blocked pursuant to § 554.201 shall be the responsibility of the owners or operators of such property, which expenses shall not be met from blocked funds.

(b) Property blocked pursuant to § 554.201 may, in the discretion of OFAC, be sold or liquidated and the net proceeds placed in a blocked interest-bearing account in the name of the owner of the property.

Subpart C—General Definitions

§ 554.300 Applicability of definitions.

The definitions in this subpart apply throughout the entire part.

§ 554.301 Blocked account; blocked property.

The terms *blocked account* and *blocked property* shall mean any account or property subject to the prohibitions in § 554.201 held in the name of a person whose property and interests in property are blocked pursuant to § 554.201, or in which such person has an interest, and with respect to which payments, transfers, exportations, withdrawals, or other dealings may not be made or effected except pursuant to a license or other authorization from OFAC expressly authorizing such action.

Note to § 554.301: See § 554.406 concerning the blocked status of property and interests in property of an entity that is 50 percent or more owned by one or more persons whose property and interests in property are blocked pursuant to § 554.201.

§ 554.302 Effective date.

The term *effective date* refers to the effective date of the applicable prohibitions and directives contained in this part as follows:

(a) With respect to a person listed in the Annex to E.O. 13712 of November 22, 2015, 12:01 a.m. eastern standard time on November 23, 2015; and

(b) With respect to a person whose property and interest in property are otherwise blocked pursuant to § 554.201, the earlier of the date of actual or constructive notice that such person's property and interests in property are blocked.

§ 554.303 Entity.

The term *entity* means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization.

§ 554.304 Financial, material, or technological support.

The term *financial, material,or technological support,* as used in Executive Order 13712 of November 22, 2015, means any property, tangible or intangible, including but not limited to currency, financial instruments, securities, or any other transmission of value; weapons or related materiel; chemical or biological agents; explosives; false documentation or identification; communications equipment; computers; electronic or other devices or equipment; technologies; lodging; safe houses; facilities; vehicles or other means of transportation; or goods. "Technologies" as used in this definition means specific information necessary for the development, production, or use of a product, including related technical data such as blueprints, plans, diagrams, models, formulae, tables, engineering designs and specifications, manuals, or other recorded instructions.

§ 554.305 Interest.

Except as otherwise provided in this part, the term *interest,* when used with respect to property (*e.g.,* "an interest in property"), means an interest of any nature whatsoever, direct or indirect.

§ 554.306 Licenses; general and specific.

(a) Except as otherwise provided in this part, the term *license* means any license or authorization contained in or issued pursuant to this part.

(b) The term *general license* means any license or authorization the terms of which are set forth in subpart E of this part or made available on OFAC's Web site: *www.treasury.gov/ofac.*

(c) The term *specific license* means any license or authorization issued pursuant to this part but not set forth in subpart E of this part or made available on OFAC's Web site: *www.treasury.gov/ofac.*

Note to § 554.306: *See* § 501.801 of this chapter on licensing procedures.

§ 554.307 OFAC.

The term *OFAC* means the Department of the Treasury's Office of Foreign Assets Control.

§ 554.308 Person.

The term *person* means an individual or entity.

§ 554.309 Property; property interest.

The terms *property* and *property interest* include, but are not limited to, money, checks, drafts, bullion, bank deposits, savings accounts, debts, indebtedness, obligations, notes, guarantees, debentures, stocks, bonds, coupons, any other financial instruments, bankers acceptances, mortgages, pledges, liens or other rights in the nature of security, warehouse receipts, bills of lading, trust receipts, bills of sale, any other evidences of title, ownership or indebtedness, letters of credit and any documents relating to any rights or obligations thereunder, powers of attorney, goods, wares, merchandise, chattels, stocks on hand, ships, goods on ships, real estate mortgages, deeds of trust, vendors' sales agreements, land contracts, leaseholds, ground rents, real estate and any other interest therein, options, negotiable instruments, trade acceptances, royalties, book accounts, accounts payable, judgments, patents, trademarks or copyrights, insurance policies, safe deposit boxes and their contents, annuities, pooling agreements, services of any nature whatsoever, contracts of any nature whatsoever, and any other property, real, personal, or mixed, tangible or intangible, or interest or interests therein, present, future, or contingent.

§ 554.310 Transfer.

The term *transfer* means any actual or purported act or transaction, whether or not evidenced by writing, and whether or not done or performed within the United States, the purpose, intent, or effect of which is to create, surrender, release, convey, transfer, or alter, directly or indirectly, any right, remedy, power, privilege, or interest with respect to any property. Without limitation on the foregoing, it shall include the making, execution, or delivery of any assignment, power, conveyance, check, declaration, deed, deed of trust, power of attorney, power of appointment, bill of sale, mortgage, receipt, agreement, contract, certificate, gift, sale, affidavit, or statement; the making of any payment; the setting off of any obligation or credit; the appointment of any agent, trustee, or fiduciary; the creation or transfer of any lien; the issuance, docketing, or filing of, or levy of or under, any judgment, decree, attachment, injunction, execution, or other judicial or administrative process or order, or the service of any garnishment; the acquisition of any interest of any nature whatsoever by reason of a judgment or decree of any foreign country; the fulfillment of any condition; the exercise of any power of appointment, power of attorney, or other power; or the acquisition, disposition, transportation, importation, exportation, or withdrawal of any security.

§ 554.311 United States.

The term *United States* means the United States, its territories and possessions, and all areas under the jurisdiction or authority thereof.

§ 554.312 United States person; U.S. person.

The term *United States person* or *U.S. person* means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

§ 554.313 U.S. financial institution.

The term *U.S. financial institution* means any U.S. entity (including its foreign branches) that is engaged in the business of accepting deposits, making, granting, transferring, holding, or brokering loans or credits, or purchasing or selling foreign exchange, securities, or commodity futures or options, or procuring purchasers and sellers thereof, as principal or agent. It includes depository institutions, banks, savings banks, trust companies, securities brokers and dealers, commodity futures and options brokers and dealers, forward contract and foreign exchange merchants, securities and commodities exchanges, clearing corporations, investment companies, employee benefit plans, and U.S. holding companies, U.S. affiliates, or U.S. subsidiaries of any of the foregoing. This term includes those branches, offices, and agencies of foreign financial institutions that are located in the United States, but not such institutions' foreign branches, offices, or agencies.

Subpart D—Interpretations

§ 554.401 [Reserved]

§ 554.402 Effect of amendment.

Unless otherwise specifically provided, any amendment, modification, or revocation of any provision in or appendix to this part or chapter or of any order, regulation, ruling, instruction, or license issued by OFAC does not affect any act done or omitted, or any civil or criminal proceeding commenced or pending, prior to such amendment, modification, or revocation. All penalties, forfeitures, and liabilities under any such order, regulation, ruling, instruction, or license continue and may be enforced as if such amendment, modification, or revocation had not been made.

§ 554.403 Termination and acquisition of an interest in blocked property.

(a) Whenever a transaction licensed or authorized by or pursuant to this part results in the transfer of property (including any property interest) away from a person whose property and interests in property are blocked pursuant to § 554.201, such property shall no longer be deemed to be property blocked pursuant to § 554.201, unless there exists in the property another interest that is blocked pursuant to § 554.201, the transfer of which has not been effected pursuant to license or other authorization.

(b) Unless otherwise specifically provided in a license or other authorization issued pursuant to this part, if property (including any property interest) is transferred or attempted to be transferred to a person whose property and interests in property are blocked pursuant to § 554.201, such property shall be deemed to be property in which such person has an interest and therefore blocked.

§ 554.404 Transactions ordinarily incident to a licensed transaction.

Any transaction ordinarily incident to a licensed transaction and necessary to give effect thereto is also authorized, except:

(a) An ordinarily incident transaction, not explicitly authorized within the terms of the license, by or with a person whose property and interests in property are blocked pursuant to § 554.201; or

(b) An ordinarily incident transaction, not explicitly authorized within the terms of the license, involving a debit to a blocked account or a transfer of blocked property.

§ 554.405 Setoffs prohibited.

A setoff against blocked property (including a blocked account), whether by a U.S. bank or other U.S. person, is a prohibited transfer under § 554.201 if effected after the effective date.

§ 554.406 Entities owned by one or more persons whose property and interests in property are blocked.

Persons whose property and interests in property are blocked pursuant to § 554.201 have an interest in all property and interests in property of an entity in which such blocked persons own, whether individually or in the aggregate, directly or indirectly, a 50 percent or greater interest. The property and interests in property of such an entity, therefore, are blocked, and such an entity is a person whose property and interests in property are blocked pursuant to § 554.201, regardless of whether the name of the entity is incorporated into OFAC's Specially Designated Nationals and Blocked Persons List (SDN List).

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 554.501 General and specific licensing procedures.

For provisions relating to licensing procedures, see part 501, subpart E of this chapter. Licensing actions taken pursuant to part 501 of this chapter with respect to the prohibitions contained in this part are considered actions taken pursuant to this part. General licenses and statements of licensing policy relating to this part also may be available through the Burundi sanctions page on OFAC's Web site: *www.treasury.gov/ofac.*

§ 554.502 [Reserved]

§ 554.503 Exclusion from licenses.

OFAC reserves the right to exclude any person, property, transaction, or class thereof from the operation of any license or from the privileges conferred by any license. OFAC also reserves the right to restrict the applicability of any license to particular persons, property, transactions, or classes thereof. Such actions are binding upon actual or constructive notice of the exclusions or restrictions.

§ 554.504 Payments and transfers to blocked accounts in U.S. financial institutions.

Any payment of funds or transfer of credit in which a person whose property and interests in property are blocked pursuant to § 554.201 has any interest that comes within the possession or control of a U.S. financial institution must be blocked in an account on the books of that financial institution. A transfer of funds or credit by a U.S. financial institution between blocked accounts in its branches or offices is authorized, provided that no transfer is made from an account within the United States to an account held outside the United States, and further provided that a transfer from a blocked account may be made only to another blocked account held in the same name.

Note to § 554.504: *See* § 501.603 of this chapter for mandatory reporting requirements regarding financial transfers. *See also* § 554.203 concerning the obligation to hold blocked funds in interest-bearing accounts.

§ 554.505 Entries in certain accounts for normal service charges authorized.

(a) A U.S. financial institution is authorized to debit any blocked account held at that financial institution in payment or reimbursement for normal service charges owed it by the owner of that blocked account.

(b) As used in this section, the term *normal service charges* shall include charges in payment or reimbursement for interest due; cable, telegraph, internet, or telephone charges; postage costs; custody fees; small adjustment charges to correct bookkeeping errors; and, but not by way of limitation, minimum balance charges, notary and protest fees, and charges for reference books, photocopies, credit reports, transcripts of statements, registered mail, insurance, stationery and supplies, and other similar items.

§ 554.506 Provision of certain legal services authorized.

(a) The provision of the following legal services to or on behalf of persons whose property and interests in property are blocked pursuant to § 554.201 or any further Executive orders relating to the national emergency declared in Executive Order 13712 of November 22, 2015, is authorized, provided that receipt of payment of professional fees and reimbursement of incurred expenses must be specifically licensed, authorized pursuant to § 554.507, which authorizes certain payments for legal services from funds originating outside the United States, or otherwise authorized pursuant to this part:

(1) Provision of legal advice and counseling on the requirements of and compliance with the laws of the United States or any jurisdiction within the United States, provided that such advice and counseling are not provided to facilitate transactions in violation of this part;

(2) Representation of persons named as defendants in or otherwise made parties to legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(3) Initiation and conduct of legal, arbitration, or administrative proceedings before any U.S. federal, state, or local court or agency;

(4) Representation of persons before any U.S. federal, state, or local court or agency with respect to the imposition, administration, or enforcement of U.S. sanctions against such persons; and

(5) Provision of legal services in any other context in which prevailing U.S. law requires access to legal counsel at public expense.

(b) The provision of any other legal services to persons whose property and interests in property are blocked pursuant to § 554.201 or any further Executive orders relating to the national emergency declared in Executive Order 13712 of November 22, 2015, not otherwise authorized in this part, requires the issuance of a specific license.

(c) Entry into a settlement agreement or the enforcement of any lien, judgment, arbitral award, decree, or other order through execution, garnishment, or other judicial process purporting to transfer or otherwise alter or affect property or interests in property blocked pursuant to § 554.201 or any further Executive orders relating to the national emergency declared in Executive Order 13712 of November 22, 2015, is prohibited unless licensed pursuant to this part.

Note to § 554.506: U.S. persons seeking administrative reconsideration or judicial review of their designation or the blocking of their property and interests in property may apply for a specific license from OFAC to authorize the release of a limited amount of blocked funds for the payment of legal fees where alternative funding sources are not available. For more information, see OFAC's *Guidance on the Release of Limited Amounts of Blocked Funds for Payment of Legal Fees and Costs Incurred in Challenging the Blocking of U.S. Persons in Administrative or Civil Proceedings,* which is available on OFAC's Web site: *www.treasury.gov/ofac.*

§ 554.507 Payments for legal services from funds originating outside the United States authorized.

(a) Receipt of payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 554.506(a) to or on behalf of any person whose property and interests in property are blocked pursuant to § 554.201 or any further Executive orders relating to the national emergency declared in Executive Order 13712 of November 22, 2015, is authorized from funds originating outside the United States, provided that the funds received by U.S. persons as payment of professional fees and reimbursement of incurred expenses for the provision of legal services authorized pursuant to § 554.506(a) do not originate from:

(1) A source within the United States;

(2) Any source, wherever located, within the possession or control of a U.S. person; or

(3) Any individual or entity, other than the person on whose behalf the legal services authorized pursuant to § 554.506(a) are to be provided, whose property and interests in property are blocked pursuant to any part of this chapter or any Executive order.

Note to § 554.507: This paragraph authorizes the blocked person on whose behalf the legal services authorized pursuant to § 554.506(a) are to be provided to make payments for authorized legal services using funds originating outside the United States that were not previously blocked. Nothing in this paragraph authorizes payments for legal services using funds in which any other person whose property and interests in property are blocked pursuant to § 554.201, any other part of this chapter, or any Executive order has an interest.

(b) *Reports.* (1) U.S. persons who receive payments in connection with legal services authorized pursuant to § 554.506(a) must submit annual reports no later than 30 days following the end of the calendar year during which the payments were received providing information on the funds received. Such reports shall specify:

(i) The individual or entity from whom the funds originated and the amount of funds received; and

(ii) If applicable:

(A) The names of any individuals or entities providing related services to the U.S. person receiving payment in connection with authorized legal services, such as private investigators or expert witnesses;

(B) A general description of the services provided; and

(C) The amount of funds paid in connection with such services.

(2) The reports, which must reference this section, are to be mailed to: Licensing Division, Office of Foreign Assets Control, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW., Annex, Washington, DC 20220.

Note to § 554.507: U.S. persons who receive payments in connection with legal services authorized pursuant to § 554.506(a) do not need to obtain specific authorization to contract for related services that are ordinarily incident to the provision of those legal services, such as those provided by private investigators or expert witnesses, or to pay for such services. Additionally, U.S. persons do not need to obtain specific authorization to provide related services that are ordinarily incident to the provision of legal services authorized pursuant to § 554.506(a).

§ 554.508 Authorization of emergency medical services.

The provision and receipt of nonscheduled emergency medical services that are otherwise prohibited by this part or any further Executive orders relating to the national emergency declared in Executive Order 13712 of November 22, 2015, are authorized.

Subparts F and G—[Reserved]

Subpart H—Procedures

§ 554.801 [Reserved]

§ 554.802 Delegation by the Secretary of the Treasury.

Any action that the Secretary of the Treasury is authorized to take pursuant to Executive Order 13712 of November 22, 2015, and any further Executive orders relating to the national emergency declared therein, may be taken by the Director of OFAC or by any other person to whom the Secretary of the Treasury has delegated authority so to act.

Subpart I—Paperwork Reduction Act

§ 554.901 Paperwork Reduction Act notice.

For approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) of information collections relating to recordkeeping and reporting requirements, licensing procedures, and other procedures, see § 501.901 of this chapter. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

APPENDIX A TO PART 554—Executive Order 13712

Executive Order 13712 of November 22, 2015

Blocking the Property of Certain Persons Contributing to the Situation in Burundi

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 212(f) of the Immigration and Nationality Act of 1952 (8 U.S.C. 1182(f)), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, find that the situation in Burundi, which has been marked by the killing of and violence against civilians, unrest, the incitement of imminent violence, and significant political repression, and which threatens the peace, security, and stability of Burundi, constitutes an unusual and extraordinary threat to the national security and foreign policy of the United States, and I hereby declare a national emergency to deal with that threat. I hereby order:

Section 1. (a) All property and interests in property that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person of the following persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in:

(i) the persons listed in the Annex to this order; and

(ii) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State:

(A) to be responsible for or complicit in, or to have engaged in, directly or indirectly, any of the following in or in relation to Burundi:

(1) actions or policies that threaten the peace, security, or stability of Burundi;

(2) actions or policies that undermine democratic processes or institutions in Burundi;

(3) human rights abuses;

(4) the targeting of women, children, or any civilians through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through other conduct that may constitute a serious abuse or violation of human rights or a violation of international humanitarian law;

(5) actions or policies that prohibit, limit, or penalize the exercise of freedom of expression or freedom of peaceful assembly;

(6) the use or recruitment of children by armed groups or armed forces;

(7) the obstruction of the delivery or distribution of, or access to, humanitarian assistance; or

(8) attacks, attempted attacks, or threats against United Nations missions, international security presences, or other peacekeeping operations;

(B) to be a leader or official of:

(1) an entity, including any government entity or armed group, that has, or whose members have, engaged in any of the activities described in subsection (a)(ii)(A) of this section; or

(2) an entity whose property and interests in property are blocked pursuant to this order;

(C) to have materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of:

(1) any of the activities described in subsection (a)(ii)(A) of this section; or

(2) any person whose property and interests in property are blocked pursuant to this order; or

(D) to be owned or controlled by, or to have acted or purported to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to this order.

(b) The prohibitions in subsection (a) of this section apply except to the extent provided by statutes, or in regulations, orders, directives, or licenses that may be issued pursuant to this order, and notwithstanding any contract entered into or any license or permit granted prior to the effective date of this order.

Sec. 2. I hereby find that the unrestricted immigrant and nonimmigrant entry into the United States of aliens determined to meet one or more of the criteria in subsection 1(a) of this order would be detrimental to the interests of the United States, and I hereby suspend entry into the United States, as immigrants or nonimmigrants, of such persons. Such persons shall be treated as persons covered by section 1 of Proclamation 8693 of July 24, 2011 (Suspension of Entry of Aliens Subject to United Nations Security Council Travel Bans and International Emergency Economic Powers Act Sanctions).

Sec. 3. I hereby determine that the making of donations of the type of articles specified in section 203(b)(2) of IEEPA (50 U.S.C. 1702(b)(2)) by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to section 1 of this order would seriously impair my ability to deal with the national emergency declared in this order, and I hereby prohibit such donations as provided by section 1 of this order.

Sec. 4. The prohibitions in section 1 of this order include but are not limited to:

(a) the making of any contribution or provision of funds, goods, or services by, to, or for the benefit of any person whose property and interests in property are blocked pursuant to this order; and

(b) the receipt of any contribution or provision of funds, goods, or services from any such person.

Sec. 5. (a) Any transaction that evades or avoids, has the purpose of evading or avoiding, causes a violation of, or attempts to violate any of the prohibitions set forth in this order is prohibited.

(b) Any conspiracy formed to violate any of the prohibitions set forth in this order is prohibited.

Sec. 6. For the purposes of this order:

(a) the term "person" means an individual or entity;

(b) the term "entity" means a partnership, association, trust, joint venture, corporation, group, subgroup, or other organization; and

(c) the term "United States person" means any United States citizen, permanent resident alien, entity organized under the laws of the United States or any jurisdiction within the United States (including foreign branches), or any person in the United States.

Sec. 7. For those persons whose property and interests in property are blocked pursuant to this order who might have a constitutional presence in the United States, I find that because of the ability to transfer funds or other assets instantaneously, prior notice to such persons of measures to be taken pursuant to this order would render those measures ineffectual. I therefore determine that for these measures to be effective in addressing the national emergency declared in this order, there need be no prior notice of a listing or determination made pursuant to section 1 of this order.

Sec. 8. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to take such actions, including the promulgation of rules and regulations, and to employ all powers granted to the President by IEEPA as may be necessary to carry out the purposes of this order. The Secretary of the Treasury may redelegate any of these functions to other officers and agencies of the United States Government consistent with applicable law. All agencies of the United States Government are hereby directed to take all appropriate measures within their authority to carry out the provisions of this order.

Sec. 9. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to determine that circumstances no longer warrant the blocking of the property and interests in property of a person listed in the Annex to this order, and to take necessary action to give effect to that determination.

Sec. 10. The Secretary of the Treasury, in consultation with the Secretary of State, is hereby authorized to submit the recurring and final reports to the Congress on the national emergency declared in this order, consistent with section 401(c) of the NEA (50 U.S.C. 1641(c)) and section 204(c) of IEEPA (50 U.S.C. 1703(c)).

Sec. 11. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 12. This order is effective at 12:01 a.m. eastern standard time on November 23, 2015.

Barack Obama

THE WHITE HOUSE,

November 22, 2015

ANNEX

1. Alain Guillaume Bunyoni [Minister of Public Security; born January 2, 1972]
2. Cyrille Ndayirukiye [Former Defense Minister; born July 8, 1954]
3. Godefroid Niyombare [Major General; born October 18, 1969]
4. Godefroid Bizimana [born April 23, 1968]

Dated March 23, 2016.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

Approved: Dated: March 29, 2016.

Adam J. Szubin,

Acting Under Secretary, Office of Terrorism and Financial Intelligence, Department of the Treasury.

[FR Doc. 2016–07851 Filed 4–5–16; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2016–0189]

RIN 1625–AA00

Safety Zone; Lower Mississippi River Mile 95.7 to 96.7; New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone from Mile Marker (MM) 95.7 to MM 96.7 above Head of Passes (AHP) on the Lower Mississippi River (LMR) on April 12, 2016. This safety zone is necessary to protect persons and vessels from potential safety hazards associated with fireworks displays on or over navigable waterways. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port New Orleans or a designated representative.

DATES: This rule is effective from 6:00 p.m. through 11:00 p.m. on April 12, 2016. Comments and related material must be received by the Coast Guard on or before May 6, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0189 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander (LCDR) James Gatz, Sector New Orleans, at (504) 365–2281 or *James.C.Gatz@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AHP Above Head of Passes

BNM	Broadcast Notice to Mariners
CFR	Code of Federal Regulations
COTP	Captain of the Port
DHS	Department of Homeland Security
FR	Federal Register
MM	Mile Marker
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Public Participation and Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov*, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this rule, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

III. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard received information about this fireworks display on or about January 27, 2016. Due to the risks associated with an aerial barge-based fireworks display taking place on and over the waterway, a safety zone is needed. It would be impracticable to publish a NPRM because the safety zone must be established on April 12, 2016. This rule provides for a comment period and comments received will be reviewed and analyzed to assist the Coast Guard in future rulemakings establishing similar safety zones. The Coast Guard will notify the public and maritime community that the safety zone will be in effect and of its enforcement periods via broadcast notices to mariners (BNM).

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Providing a full 30-days notice would be impracticable because immediate action is needed to protect persons and property from the hazards associated with an aerial fireworks display taking place on and over the waterway.

IV. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. On April 12, 2016, a fireworks display will be launched from a barge positioned in the waterway adjacent to Mardi Gras World, an event venue located at MM 96.2 AHP on the Lower Mississippi River, in a high commercial traffic area near a tight river bend. Therefore, the Coast Guard has determined that a safety zone is needed to ensure safe navigation for all those in the vicinity of these fireworks displays.

V. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone on the Lower Mississippi River, for one hour during the evening of April 12, 2016, to occur between 6 and 11 p.m. The safety zone will include the entire width of the Lower Mississippi River in New Orleans, LA from MM 95.7 to MM 96.7 AHP. Entry into this zone is prohibited unless permission has been granted by the COTP New Orleans, or a designated representative.

The COTP New Orleans will inform the public through BNMs of the one-hour enforcement period for the safety zone as well as any changes in the planned schedule. Mariners and other members of the public may also contact Coast Guard Sector New Orleans Command Center to inquire about the status of the safety zone, at (504) 365–2200.

VI. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. This safety zone will only restrict navigation on the Lower Mississippi River from MM 95.7 to MM 96.7 AHP, for approximately one hour on April 12, 2016. Due to the limited scope and short duration of the safety zone, the impacts on routine navigation are expected to be minimal.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit the safety zone area during the periods of enforcement. The safety zone will not have a significant economic impact on a substantial number of small entities because they are limited in scope and will be in effect for a short period of time. Before the enforcement periods, the Coast Guard COTP will issue maritime advisories widely available to waterway users. Deviation from the safety zone established through this rulemaking may be requested from the appropriate COTP and requests will be considered on a case-by-case basis.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone for all waters of the Lower Mississippi River from MM 95.7 to MM 96.7 AHP. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0189 to read as follows:

§ 165.T08–0189 Safety Zones; Lower Mississippi River Miles 95.7 to 96.7; New Orleans, LA.

(a) *Location.* The following area is a safety zone: All waters of the Lower Mississippi River from mile marker 95.7 to mile marker 96.7 Above Head of Passes, New Orleans, LA.

(b) *Enforcement period.* This rule is enforceable on April 12, 2016, for one hour in the evening to occur between 6:00 p.m. and 11:00 p.m. The one-hour enforcement period will be noticed as indicated under paragraph (d) of this section.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) New Orleans or designated personnel. Designated personnel include commissioned, warrant and petty officers of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans. For this rule the COTP's designated representative is Vessel Traffic Service Lower Mississippi River.

(2) Vessels requiring deviation from this rule must request permission from the COTP New Orleans or a COTP New Orleans designated representative. They may be contacted on VHF–FM Channel 16 or 67, or through Vessel Traffic Service Lower Mississippi River at 504–365–2415.

(3) Persons and vessels permitted to deviate from this safety zone regulation and enter the restricted area must transit at the slowest safe speed and comply with all lawful directions issued by the COTP New Orleans or the designated representative.

(d) *Information broadcasts.* The COTP New Orleans or a COTP New Orleans designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone as well as any changes in the planned schedule.

Dated: March 30, 2016.

W.R. Arguin Jr.,

Captain, U.S. Coast Guard, Acting Captain of the Port New Orleans.

[FR Doc. 2016–07729 Filed 4–5–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP09

Health Care for Certain Children of Vietnam Veterans and Certain Korea Veterans—Covered Birth Defects and Spina Bifida

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rule adopts as final a proposed rule of the Department of Veterans Affairs (VA) to amend its regulations concerning the provision of health care to birth children of Vietnam veterans and veterans of covered service in Korea diagnosed with spina bifida, except for spina bifida occulta, and certain other birth defects. In the proposed rule published on May 15, 2015, VA proposed changes to more clearly define the types of health care VA provides, including day health care and health-related services, which we defined as homemaker or home health aide services that provide assistance with Activities of Daily Living or Instrumental Activities of Daily Living that have therapeutic value. We also proposed changes to the list of health care services that require preauthorization by VA. This final rule addresses comments received from the public and adopts as final the proposed rule, without change.

DATES: *Effective Date:* This rule is effective on May 6, 2016.

FOR FURTHER INFORMATION CONTACT: Karyn Barrett, Director, Program Administration Directorate, Chief Business Office Purchased Care (10NB3), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420, (303) 331–7500. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Chapter 18 of title 38, United States Code, provides for benefits for certain birth children of Vietnam veterans and veterans of covered service in Korea who have been diagnosed with spina bifida, except spina bifida occulta, and certain other birth defects. These benefits include: (1) Monthly monetary allowances for various disability levels; (2) health care; and (3) vocational training and rehabilitation. VA's regulations concerning health care for children authorized under this chapter are published at 38 CFR 17.900 through 17.905.

On May 15, 2015, VA published a proposed rule to more clearly define the types of healthcare VA provides, including day healthcare and health-related services, which VA would define as homemaker or home health aide services that provide assistance with Activities of Daily Living or Instrumental Activities of Daily Living that have therapeutic value; and to make changes to the list of health care services that require preauthorization by VA. (80 FR 27878). The comment period closed on June 14, 2015. We received ten comments, which were all generally supportive. However, the commenters raised several issues regarding beneficiaries covered by this rulemaking, specific services provided, definitions included in the proposed rule, and provision of health care through non-VA care (care in the community). We respond to these comments below and adopt as final the proposed rule, without change.

Scope of the Rulemaking

One commenter stated that children of Vietnam veterans who have spina bifida may have children of their own, and VA should also provide care to grandchildren of Vietnam veterans who have spina bifida. The commenter stated that according to the US National Library of Medicine, spina bifida is likely caused by the interaction of multiple genetic and environmental factors, and that genetic changes in individuals with spina bifida may increase the risk of neural tube defects in the subsequent generation. The commenter stated that if a child with spina bifida can establish that the grandfather was exposed to herbicides during the Vietnam War, that child should also be covered.

Another commenter stated that children of Air Force active duty servicemembers and reservists who were exposed to Agent Orange while flying C–123 aircraft both during the Vietnam War and the post-war period should also be covered. The commenter noted that these servicemembers flew out of air bases in Thailand and Clark Air Base in the Philippine Islands, and some of the airplanes potentially contaminated by Agent Orange remained in service after the war.

In response to the first comment, VA does not have statutory authority to provide health care to grandchildren of Vietnam veterans who may have spina bifida. VA's authority to provide health care to children with spina bifida or other covered birth defects is limited by statute. A "child" covered under this statute is defined at 38 U.S.C. 1831(1) as an individual, regardless of age or marital status, who is the natural child of a Vietnam veteran, and was conceived after the date on which that veteran first entered the Republic of Vietnam during the Vietnam era; or, is the natural child of a veteran of covered service in Korea (as determined for purposes of 38 U.S.C. 1821), and was conceived after the date on which that veteran first entered service described in 38 U.S.C. 1821(c).

With respect to the second comment, VA also does not have the authority to extend benefits under 38 U.S.C. Chapter 18 to children of veterans who did not serve in the Republic of Vietnam during the Vietnam era or who did not have certain service in Korea. "Vietnam veteran" is defined at 38 U.S.C. 1831(2) to mean an individual who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era, without regard to the characterization of that individual's service. The "Vietnam era" is defined at 38 U.S.C. 1831(3) as ending on May 7, 1975. A veteran of covered service in Korea is any individual, without regard to the characterization of that individual's service, who served in the active military, naval, or air service in or near the Korean demilitarized zone (DMZ), as determined by the Secretary in consultation with the Secretary of Defense, during the period beginning on September 1, 1967, and ending on August 31, 1971; and is determined by VA, in consultation with the Department of Defense, to have been exposed to an herbicide agent during such service in or near the Korean demilitarized zone. 38 U.S.C. 1821(c). To the extent a veteran who flew in a C–123 is also a veteran with covered service defined in 38 U.S.C. 1831(2) and has a child covered by 38 U.S.C. 1831(1), however, the child would be eligible for benefits under Chapter 18.

In further response to the comment regarding reservists and servicemembers who flew in C–123 aircraft, we note that VA does have authority in certain other circumstances to extend benefits to veterans who did not serve in those defined areas or time periods, but may have been exposed to Agent Orange. This authority is unrelated to benefits furnished to eligible children under 38 U.S.C. Chapter 18 but we briefly discuss it here because a recent VA rulemaking is relevant to the second public comment. On June 19, 2015, VA published an interim final rule (80 FR 35248) extending the presumption of herbicide exposure and presumption of service connection to individuals who performed service in the Air Force or Air Force Reserve under circumstances in which the individual concerned regularly and repeatedly operated, maintained, or served onboard C–123 aircraft known to have been used to spray an herbicide agent during the Vietnam era. The June 2015 interim final rule thus covers servicemembers who were potentially exposed to Agent Orange during periods after the end of the Vietnam War, and in regions outside of Vietnam. VA determined that the presumption of service connection should be extended to these servicemembers based on a January 2015 report from the National Academies of Sciences, Engineering, and Medicine's Institute of Medicine (IOM) titled "Post-Vietnam Dioxin Exposure in Agent Orange–Contaminated C–123 Aircraft." In that report the IOM noted that between 1972 and 1982, approximately 1,500 to 2,100 U.S. Air Force Reserve personnel trained and worked on C–123 aircraft that previously had been used to spray herbicides, including Agent Orange, during Operation Ranch Hand. Based on a review of the evidence, IOM concluded that it was plausible that Air Force reservists flying C–123 aircraft used in Operation Ranch Hand were exposed to Agent Orange.

We make no changes based on these comments.

Definitions

One commenter asked whether the proposed addition of day health care to the list of health care services would require the beneficiary to transfer to a group home. In the proposed rule we defined day health care to mean a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care services contemplated under this proposal are non-residential and equivalent to adult day health care provided to disabled veterans under 38 CFR 17.111(c)(1). These would not require the beneficiary to relocate to a group home. The essential features are the therapeutic focus of the day health care services and provision of these services in a congregate setting. The addition of day health care to the list of covered health care services augments rather than contracts the options available. Day health care is an alternative care setting that can allow some beneficiaries who require long term care services to remain in their homes rather than be institutionalized in a nursing home. Such beneficiaries typically require support for some, but not all, Activities of Daily Living (ADLs), such as bathing, dressing or feeding. In many cases, a family member may provide the beneficiary with much of their care, but require additional support for some ADLs. By filling these gaps, day health care can allow these beneficiaries to remain in their homes and communities for additional months or even years. Day health care programs can help caregivers to meet their other professional and family obligations, or provide a well-deserved respite, while their loved ones are participating in the program.

Two commenters urged VA to allow payment for homemakers and home health aides to shop for groceries outside of the home. Homemaker and home health aide (H/HHA) services are health-related services. VA provides health-related services, including H/HHA services, to veterans under 38 U.S.C. 1720C. We proposed to provide H/HHA services to spina bifida beneficiaries similar to that provided to veterans, to the extent allowed by law. Under 38 U.S.C. 1720C, VA may provide H/HHA to veterans in "noninstitutional settings." This includes services performed outside the home, such as grocery shopping and escorting the veteran to necessary appointments. VA may not provide such services to beneficiaries under the Spina Bifida Health Care Benefits Program, health-related services for spina bifida beneficiaries are included as a component of home care. Home care is defined at 38 U.S.C. 1803(c)(3) as outpatient care, habilitative and rehabilitative care, preventive health services, and health-related services furnished to an individual in the individual's home or other place of residence. This definition specifically limits the provision of health-related services under 38 U.S.C. 1803 to those services furnished within the home or other place of residence. Grocery shopping, which is an H/HHA type of health-related service performed outside the home or other place of residence, cannot be provided due to this statutory restriction that applies to the Spina Bifida Health Care Benefits Program, but not to VA's authorities to provide care to veterans.

One commenter supported the proposed rule, but urged us to amend the definition of "other place of residence." As noted above, home care, including health-related services such as H/HHA services, is provided in the individual's home or other place of residence. We proposed to define other place of residence to include an assisted living facility or residential group home. Assisted living facilities and residential group homes are appropriate for individuals who do not require the level of care provided in a nursing home, and VA believes that providing home care in assisted living facilities and residential group homes will allow individuals to retain a greater level of independence and quality of life, and delay or prevent any need for nursing home care. While VA may provide services to an individual residing in an assisted living facility or residential group home, we do not have the statutory authority to pay for placement in such facility. The types of alternatives to home care that VA may provide under 38 U.S.C. 1803 are nursing home care, hospital care, and respite care. The commenter suggested amending the definition of "other place of residence" to state that "placement in such facility or home is covered to the extent that the facility or home provides covered care or services." The commenter stated that this would clarify that VA can provide for placement in an assisted living facility or residential group home to the extent that such location provides aspects of care or services covered under 38 U.S.C. 1803. We do not agree. Payment for placement in an assisted living facility or residential group home is distinctly different than providing for care and services rendered in such facility. While VA cannot do the former, we may do the latter to the extent allowed by law. VA believes that the suggested language would lead to confusion as it implies that VA can cover, to some extent, placement in an assisted living facility or residential group home.

One commenter asked for clarification of what long-term care means as that term applies to H/HHA services. Specifically, the commenter asked whether a spina bifida beneficiary would be entitled to receive H/HHA services around the clock and indefinitely. One commenter asked whether there would be a limit on the number of hours of H/HHA services that a beneficiary may receive. As noted above, H/HHA services provided to spina bifida beneficiaries are similar to that provided to veterans, to the extent allowed by law. Under 38 U.S.C. 1720C, VA is authorized to provide veterans with health-related services in a non-institutional setting. The total cost of providing such services or in-kind assistance to any veteran in any fiscal year may not exceed 65 percent of the cost that would have been incurred by VA during that fiscal year if the veteran had been furnished, instead, nursing home care under 38 U.S.C. 1710. See 38 U.S.C. 1720C(d). The same limitation is applied currently to H/HHA services provided to spina bifida beneficiaries and will continue to apply under this rule. Consistent with this limitation, H/HHA services will be provided to spina bifida beneficiaries if medically necessary.

The commenter also requested clarification on what type of health care provider must prescribe H/HHA services. These services must be prescribed by an approved health care provider. Under § 17.900, "approved health care provider" means a health care provider currently approved by the Center for Medicare and Medicaid Services (CMS), Department of Defense TRICARE Program, Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), Joint Commission, or currently approved for providing health care under a license or certificate issued by a governmental entity with jurisdiction.

The commenter also raised several procedural issues that are beyond the scope of this rulemaking.

We make no changes based on these comments.

Miscellaneous

One commenter stated that health care should be provided directly by VA health care providers rather than through care in the community. However, children with covered birth defects or spina bifida require specialty care that may not be available in a VA medical center, and requiring the beneficiary to commute to a VA medical facility could impose an undue burden on the caregiver. Here, care in the community ensures that the beneficiary receives necessary specialty medical care in a timely manner, and eliminates the need to travel to the nearest VA medical center to obtain that care.

Based on the rationale set forth in the preamble to the proposed rule and in this preamble, VA is adopting the proposed rule as a final rule, with no changes.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi).

This final rule will impose the following amended information collection requirements. Preauthorization from VA under 38 CFR 17.902(a) is required for certain services or benefits under §§ 17.900 through 17.905. Information collection under this rule is approved under OMB control number 2900–0219. VA is making a minor modification to this information collection by requiring preauthorization for mental health services only for outpatient mental health services, and only when those services are provided in excess of 23 visits in a calendar year. VA also adds day health care provided as outpatient care and homemaker services to the list of services or benefits that must receive preauthorization. VA anticipates that the decrease in the number of beneficiaries that must request preauthorization for mental health services will be offset by the number of beneficiaries that will request preauthorization for day health care. Therefore, we believe that there will be little, if any, change in the total burden hours as a result of this modification. As required by the 44 U.S.C. 3507(d), VA submitted these information collection amendments to OMB for its review, and the information collection is pending OMB approval. Notice of OMB approval for this information collection will be published in a future **Federal Register** document.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document on March 31, 2016, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: April 1, 2016.

William F. Russo,

Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.900 by:

■ a. In the definition of "Approved health care provider" removing "Joint Commission on Accreditation of Health Care Organizations (JCAHO)" from the first sentence and adding, in its place, "The Joint Commission".

■ b. Adding in alphabetical order a definition of "Day health care";.

■ c. In the definition of "Health care" adding "long-term care," to the first sentence immediately after "hospital care,".

■ d. Adding in alphabetical order definitions of "Health-related services", "Home health aide services", "Homemaker services", "Long-term care", and "Other place of residence";

■ e. In the definition of "Outpatient care" adding "day health care and" immediately after the word "including"; and

■ f. Revising the definition of "Respite care".

The additions and revision read as follows:

§ 17.900 Definitions.

* * * * *

Day health care means a therapeutic program prescribed by an approved health care provider that provides necessary medical services, rehabilitation, therapeutic activities, socialization, nutrition, and transportation services in a congregate setting. Day health care may be provided as a component of outpatient care or respite care.

* * * * *

Health-related services means homemaker or home health aide services furnished in the individual's home or other place of residence to the extent that those services provide assistance with Activities of Daily Living and Instrumental Activities of Daily Living that have therapeutic value.

* * * * *

Home health aide services is a component of health-related services providing personal care and related support services to an individual in the home or other place of residence. Home health aide services may include assistance with Activities of Daily Living such as: Bathing; toileting; eating; dressing; aid in ambulating or transfers; active and passive exercises; assistance with medical equipment; and routine health monitoring. Home health aide services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

Homemaker services is a component of health-related services encompassing certain activities that help to maintain a safe, healthy environment for an individual in the home or other place of residence. Such services contribute to the prevention, delay, or reduction of risk of harm or hospital, nursing home, or other institutional care. Homemaker services include assistance with personal care; home management; completion of simple household tasks; nutrition, including menu planning and meal preparation; consumer education; and hygiene education. Homemaker services may include assistance with Instrumental Activities of Daily Living, such as: Light housekeeping; laundering; meal preparation; necessary services to maintain a safe and sanitary environment in the areas of the home used by the individual; and services essential to the comfort and cleanliness of the individual and ensuring individual safety. Homemaker services must be provided according to the individual's written plan of care and must be prescribed by an approved health care provider.

* * * * *

Long-term care means home care, nursing home care, and respite care.

* * * * *

Other place of residence includes an assisted living facility or residential group home.

* * * * *

Respite care means care, including day health care, furnished by an approved health care provider on an intermittent basis for a limited period to an individual who resides primarily in a private residence when such care will help the individual continue residing in such private residence.

* * * * *

■ 3. Amend § 17.902 by:

■ a. Revising the first three sentences of paragraph (a) introductory text; and

■ b. At the end of the section, removing "2900–0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900–0219".

The revisions read as follows:

§ 17.902 Preauthorization.

(a) Preauthorization from VA is required for the following services or benefits under §§ 17.900 through 17.905: Rental or purchase of durable medical equipment with a total rental or purchase price in excess of $300, respectively; day health care provided as outpatient care; dental services; homemaker services; outpatient mental health services in excess of 23 visits in a calendar year; substance abuse treatment; training; transplantation services; and travel (other than mileage at the General Services Administration rate for privately owned automobiles). Authorization will only be given in spina bifida cases where it is demonstrated that the care is medically necessary. In cases of other covered birth defects, authorization will only be given where it is demonstrated that the care is medically necessary and related to the covered birth defects. * * *

* * * * *

■ 4. Amend § 17.903 by:

■ a. In paragraph (a)(1), adding a second sentence; and

■ b. At the end of the section, removing "2900–0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900–0219".

The addition reads as follows:

§ 17.903 Payme.

(a)(1) * * * For those services or benefits covered by §§ 17.900 through 17.905 but not covered by CHAMPVA we will use payment methodologies the same or similar to those used for equivalent services or benefits provided to veterans.

* * * * *

§ 17.904 [Amended]

■ 5. Amend § 17.904 by, at the end of the section, removing "2900–0578" from the notice of the Office of Management and Budget control number and adding, in its place, "2900–0219".

[FR Doc. 2016–07897 Filed 4–5–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0338 and EPA–HQ–OPP–2015–0339; FRL–9942–32]

Hexythiazox; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends tolerances for residues of hexythiazox in or on citrus and cotton. Gowan Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective April 6, 2016. Objections and requests for hearings must be received on or before June 6, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0338 and EPA–HQ–OPP–2015–0339, are available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0338 and EPA–HQ–OPP–2015–0339 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 6, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0338 and EPA–HQ–OPP–2015–0339, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-for Tolerance

In the **Federal Register** of July 17, 2015 (80 FR 42462) (FRL–9929–13), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 5F8346 and PP 5F8356) by Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569. The petitions requested that tolerances currently listed in 40 CFR 180.448 be amended for residues of the insecticide hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on citrus, dried pulp at 0.6 parts per million (ppm); citrus, oil at 26 ppm; fruit, citrus, group 10 at 0.6 ppm; cotton gin byproducts at 15 ppm; and cotton, undelinted seed at 0.5 ppm. That document referenced a summary of the petitions prepared by Gowan Company, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revoked citrus, dried pulp tolerance as it is covered by the recommended fruit, citrus, group 10–10 tolerance. For citrus oil, EPA revised the tolerance to 25 ppm and for cotton undelinted seed to 0.4

ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for hexythiazox including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with hexythiazox follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Hexythiazox has low acute toxicity by oral, dermal and inhalation routes of exposure. It is not a dermal irritant, is negative for dermal sensitization and produces only mild eye irritation. Hexythiazox is associated with toxicity of the liver and adrenals following subchronic and chronic exposure to dogs, rats and mice, with the dog being the most sensitive species. The prenatal developmental studies in rabbits and rats and the two-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* or postnatal exposure to hexythiazox. Reproductive toxicity was not observed. There is no concern for immunotoxicity or neurotoxicity following exposure to hexythiazox. The toxicology database for hexythiazox does not show any evidence of treatment-related effects on the immune system. Hexythiazox is classified as "likely to be carcinogenic to humans;" however, the weight of evidence indicates that assessing chronic risk using the chronic population adjusted dose will be protective for any potential carcinogenic effects. Since the effects seen in the study that serves as the basis for the chronic PAD occurred at doses substantially below the lowest dose that induced tumors, the chronic PAD is considered protective of all chronic effects including potential carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by hexythiazox as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document: Hexythiazox. Human Health Risk Assessment to Support Amended Uses on Cotton and Citrus in docket ID number EPA–HQ–OPP–2015–0338 or EPA–HQ–OPP–2015–0339.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*. A summary of the toxicological endpoints for hexythiazox used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HEXYTHIAZOX FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	No risk is expected from this exposure scenario as no hazard was identified in any toxicity study for this duration of exposure.		
Chronic dietary (All populations)	NOAEL = 2.5 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.025 mg/kg/day. cPAD = 0.025 mg/kg/day	1-year toxicity feeding study—Dog LOAEL = 12.5 mg/kg/day based on increased absolute and relative adrenal weights and associated adrenal histopathology.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR HEXYTHIAZOX FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 30 mg/kg/day UF_A = 10x. UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	2-generation reproduction study—Rat. LOAEL = 180 mg/kg/day based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights. Co-critical 13-Week Oral Toxicity Study—Rat. NOAEL = 5.5 mg/kg/day LOAEL = 38 mg/kg/day, based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zona fasciculata. @397.5/257.6 mg/kg/day, decreased body-weight gain in females, slight swelling of hepatocytes in central zone (both sexes), increased incidence of glomerulonephrosis in males, increased adrenal weights.
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months).	Oral study NOAEL = 30 mg/kg/day (inhalation absorption rate = 100%). UF_A = 10x UF_H = 10x	LOC for MOE = 100	2-generation reproduction study—Rat. LOAEL = 180 mg/kg/day based on decreased pup body weight during lactation and delayed hair growth and/or eye opening, and decreased parental body-weight gain and increased absolute and relative liver, kidney, and adrenal weights. Co-Critical 13-Week Feeding Study—Rat. LOAEL = 38.1 mg/kg/day, based on increased absolute and relative liver weights in both sexes, increased relative ovarian and kidney weights, and fatty degeneration of the adrenal zona fasciculata.
Cancer (Oral, dermal, inhalation).	Classification: "Likely to be Carcinogenic to Humans". Insufficient evidence to warrant a quantitative estimation of human risk using a cancer slope factor based on the common liver tumors (benign and malignant) observed only in high dose female mice, and benign mammary gland tumors of no biological significance, observed only in high dose male rats in the absence of mutagenic concerns. The chronic RfD is protective of all chronic effects including potential carcinogenicity of hexythiazox.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to hexythiazox, EPA considered exposure under the petitioned-for tolerances as well as all existing hexythiazox tolerances in 40 CFR 180.448. EPA assessed dietary exposures from hexythiazox in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for hexythiazox; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the U.S. Department of Agriculture's 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues, assumed 100 percent crop treated (PCT), and incorporated DEEM default processing factors when processing data were not available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to hexythiazox. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for hexythiazox. Tolerance-level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for hexythiazox in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of hexythiazox. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the Surface Water Concentration Calculator, the estimated drinking water concentrations (EDWCs) of hexythiazox for chronic exposures for non-cancer assessments are estimated to be 4.3 parts per billion (ppb) for surface water. Since groundwater residues are not expected to exceed surface water residues, surface water residues were used in the dietary risk assessment. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.*, for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Hexythiazox is currently registered for the following uses that could result in residential exposures: Ornamental plantings, lawns, recreational sites such as campgrounds and golf courses, turf, and fruit and nut trees in residential settings. EPA assessed residential exposure using the following assumptions:

Residential handler exposures are expected to be short-term (1 to 30 days) via either the dermal or inhalation routes of exposures. Intermediate-term exposures are not likely because of the intermittent nature of applications by residential applicators. Since hexythiazox does not pose a significant dermal risk, a quantitative dermal risk assessment was not performed and handler margins of exposure (MOE) were calculated for the inhalation route of exposure only.

Both adults and children may be exposed to hexythiazox residues from contact with treated lawns or treated residential plants. Post-application exposures are expected to be short-term (1 to 30 days) in duration for most exposure scenarios, and intermediate-term (1 to 6 months) in duration for soil ingestion only due to the aerobic soil metabolism half-life for hexythiazox. Adult post-application exposures were not assessed since no quantitative dermal risk assessment is needed for hexythiazox and inhalation exposures are typically negligible in outdoor settings. The exposure assessment for children included incidental oral exposure resulting from transfer of residues from the hands or objects to the mouth, and from incidental ingestion of soil.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found hexythiazox to share a common mechanism of toxicity with any other substances, and hexythiazox does not appear to produce a toxic metabolite. For the purposes of this tolerance action, therefore, EPA has assumed that hexythiazox does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal development studies in rabbits and rats and the two-generation reproduction study in rats showed no indication of increased susceptibility to *in utero* and/or postnatal exposure to hexythiazox.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for hexythiazox is complete.

ii. There is no indication that hexythiazox is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that hexythiazox results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to hexythiazox in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by hexythiazox.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate- and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect, resulting from a single oral exposure, was identified and no acute dietary endpoint was selected. Therefore, hexythiazox is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to hexythiazox from food and water will utilize 81% of the cPAD for children 1 to 2 years of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of hexythiazox is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,300 for children and 9,900 for adults. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic

exposure to food and water (considered to be a background exposure level).

Hexythiazox is currently registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to hexythiazox.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 1,500 for children and 9,900 for adults. Because EPA's level of concern for hexythiazox is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.C.1.iii., EPA concluded that regulation based on the chronic reference dose will be protective for both chronic and carcinogenic risks. As noted in this unit, there are no chronic risks of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to hexythiazox residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography method with ultraviolet detection (HPLC/UV)) is available to enforce the tolerance expression. This method is listed in the U.S. EPA Index of Residue Analytical methods under hexythiazox as method AMR–985–87.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for residues of hexythiazox on citrus, fruits but not for cotton. The Codex plant residue definition is for hexythiazox as opposed to the U.S. definition which includes hexythiazox plus metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety. The differences in U.S. and Codex residue definitions prohibits harmonization.

C. Revisions to Petitioned-for Tolerances

Although the petitioner requested an amended tolerance for citrus, dried pulp at 0.6, the Agency has determined that no such tolerance is necessary because that commodity is covered by the established citrus group 10–10 tolerance. The Agency is revising the tolerance for citrus oil to 25 ppm based on the following: By multiplying the citrus oil processing factor (104X) from the 2006 processing study (D334889, 07/03/2006, T. Bloem) by the highest average field trial (HAFT) residue for lemons (0.243 ppm) from the submitted citrus study since lemons are the citrus crop that produced the highest residues.

As noted in its most recent crop group rulemaking in the **Federal Register** of August 22, 2012 (77 FR 50617) (FRL–9354–3), EPA generally does not establish new tolerances under pre-existing crop groups that have been updated. EPA updated crop group 10 in 2010, making the new group 10–10. Therefore, EPA is establishing citrus fruit group tolerances for group 10–10, rather than crop group 10 as requested.

The Agency is amending the tolerance for cotton, undelinted seed at 0.4 ppm based on the available cotton data that reflect a national use at the label specified 35 day pre-harvest internal (PHI) to calculate the 0.4 ppm tolerance.

V. Conclusion

Therefore, tolerances are amended for residues of hexythiazox and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety, in or on citrus, oil at 25 ppm; fruit, citrus, group 10–10 at 0.6 ppm; cotton, gin byproducts at 15 ppm; cotton, undelinted seed at 0.4 ppm. The current citrus, dried pulp tolerance is revoked because it is unnecessary due to the establishment of the fruit, citrus, group 10–10 tolerance.

VI. Statutory and Executive Order Reviews

This action amends tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 22, 2016.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.448:

■ i. Add alphabetically the entries for "Cotton, gin byproducts" and "Cotton, undelinted seed" to the table in paragraph (a).

■ ii. Remove the entry for "Citrus, dried pulp" from the table in paragraph (a).

■ iii. Revise the entry for "Citrus, oil" in the table in paragraph (a).

■ iv. Remove the entries for "Cotton, gin byproducts, CA and AZ only", and "Cotton, undelinted seed, CA and AZ only" from the table in paragraph (c).

■ v. Revise the entry for "Fruit, citrus group 10 (CA, AZ, TX only)" in the table in paragraph (c).

The additions and revisions read as follows:

§ 180.448 Hexythiazox; tolerances for residues.

(a) *General.* * * *

Commodity	Parts per million
* * * * *	
Citrus, oil	25
* * * * *	
Cotton, gin byproducts	15
Cotton, undelinted seed	0.4
* * * * *	

(c) *Tolerances with regional registrations.* * * *

Commodity	Parts per million
* * * * *	
Fruit, citrus group 10–10 (CA, AZ, TX only)	0.6
* * * * *	

* * * * *

[FR Doc. 2016–07661 Filed 4–5–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 13–49; FCC 16–24]

Unlicensed—National Information Infrastructure, Order on Reconsideration

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document responds to seven petitions for reconsideration of certain rules adopted in the *First Report and Order* (First R&O) in this proceeding, the Commission amends its Part 15 rules governing the operation of unlicensed National Information Infrastructure (U–NII) devices in the 5 GHz band. These rule changes are intended to make broadband technologies more widely available for consumers and businesses by temporarily increasing the in-band power limits and permanently increasing the out-of- band power limits for certain U–NII–3 band devices. The Commission also takes steps to maintain certain levels of interference protection for other authorized operations within the 5 GHz band.

DATES: Effective May 6, 2016.

FOR FURTHER INFORMATION CONTACT: Aole Wilkins, Office of Engineering and Technology, (202) 418–2406, email: *Aole.Wilkins@fcc.gov,* TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum Opinion & Order* (*MO&O*), ET Docket No. 13–49, FCC 16–24, adopted March 1, 2015, and released March 2, 2016. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of Memorandum Opinion and Order

A. U–NII–3 Band Proposals for Changes to the First R&O

1. Prior to adoption of the *First R&O,* the FCC's rules permitted the certification of devices that operate in the 5.725–5.85 GHz (U–NII–3) band under two different rule sections (*i.e.* Sections 15.247 and 15.407). In some instances, and especially for devices that operate in point-to-point configurations with high gain antennas, the old Section 15.247 out-of-band emission (OOBE) limits were as much as 47 dB more permissive than the Section 15.407 OOBE limits and, therefore devices certified under the old limits were significantly more likely to create harmful interference to other operations. In the *First R&O,* the Commission adopted a consolidated set of rules for the 5.725–5.85 GHz band devices under the Section 15.407 U–NII rules to resolve interference issues to Terminal Doppler Weather Radar (TDWR) and other radar facilities in the adjacent band. In the *First R&O,* the Commission recognized that point-to-point systems utilizing high gain transmit antennas certified under the old Section 15.247 requirement may have to be modified to comply with the lower OOBE limit required for operation under Section 15.407. The Commission stated that manufacturers had the flexibility to determine how they should meet the lower OOBE limits, whether by reducing output power, decreasing the transmit antenna gain, or utilizing improved bandpass filters.

2. In response to the *First R&O,* the Commission received several petitions for reconsideration of its decision. Petitioners, mainly manufacturers and operators of high gain point-to-point communication systems, ask that the Commission's decision to impose more restrictive OOBE limits for devices in

the U–NII–3 band should either be reversed or modified. The petitions express concerns regarding increased equipment costs, sustainability of existing service, and diminished performance of devices in the band. The petitioners' state that the limits adopted in the *First R&O* will prevent remote communities from receiving access to critical services and will render required upgrades costly and unobtainable. Numerous comments were filed in general support of the petitions requesting modification of the new OOBE limits.

3. *Consensus Certification Proposal.* This approach proposed multiple equipment certification requirements for point-to-point equipment intended to reduce the probability of harmful interference while minimizing burdens on manufacturers and users. Under this approach, users would verify that a device's location and transmission direction would not cause interference with TDWRs; allow equipment that supports dynamic frequency selection (DFS) in the U–NII–2C band to automatically allow increased emissions from the U–NII–3 band in frequency ranges where no radars are detected; and create a 5 km radius exclusion zone around each TDWR and prohibit the peak of a transmitter's antenna beam from intersecting with such exclusion zones.

4. *Ubiquiti Proposal.* Under this approach, for transmitters operating in the 5.725–5.85 GHz band, all out-of-band emissions be limited to a level of −27 dBm/MHz at 75 MHz beyond the band edge, increasing linearly to 10 dBm/MHz at 25 MHz beyond the band edge, and from 25 MHz beyond the band edge, increasing linearly to a level of 17 dBm/MHz at the band edge.

5. *Joint Emissions Proposal.* This approach closely resembled the Ubiquiti proposal, but would provide further relief from the OOBE limits in the 5 MHz closest to the band edge by allowing emissions to increase linearly to a maximum level of 27 dBm/MHz.

6. *Broadcom Proposal.* This approach mimics the Ubiquiti and the Joint Emissions Proposals, but would roll off emissions to −17 dBm/MHz at 75 MHz beyond the band edge. Broadcom believes the change is necessary because of an artifact that occurs outside of the in-band wanted emissions in certain of their current model chips. These spurious emissions are unintentional artifacts in the design of their current chipsets and did not create a compliance issue until the UNII rules were modified in 2014. Broadcom asserts that the mask can be modified to accommodate their circumstance while continuing to provide the same level of interference protection to TDWRs.

7. The Commission believes that the Joint Emissions Proposal best addresses the need for amended rules in the U–NII–3 band. It recognizes that, without further accommodation, point-to-point systems that utilize high gain transmit antennas with full permissible output power may not readily be able to comply with the OOBE limit adopted in the *First R&O.* Based on the record, in order for today's systems to suppress emissions to the degree required by the existing OOBE limits, they would require prohibitively expensive equipment modifications which would add an undue amount of weight to the devices. The Commission believes that the rules we are adopting here will allow point-to-point systems to operate, while avoiding harmful out of band interference, without excessive difficulty or cost. Unlike the Consensus Certification Proposal, which would apply different OOBE requirements based on a variety of situations, including the location of each installation relative to TDWRs, the approach adopted here will provide a single, consistent OOBE requirement for all equipment. Also unlike the Consensus Certification Proposal, the chosen approach will also avoid the need for onerous oversight by the Commission and it will, ultimately, better protect TDWRs against harmful interference because it is simpler to administer and enforce at the certification level. The Commission does not believe that Broadcom's difficulty in meeting the new limits for its current product is sufficient reason to further relax the OOBE limits. Instead, the Commission provides relief to all manufacturers by allowing some extra time to certify and to bring newly compliant devices into the marketplace.

8. As demonstrated in Ubiquiti's *ex parte* presentation, the proposed emission limits closely reflect the emissions mask seen in devices that are currently being sold, and thus the manufacturers may have a reduced need to undergo extensive redesigns to their equipment. Additionally, this revision should provide relief for wireless Internet service providers (WISPSs) and operators of long range point-to-point U–NII–3 equipment by reducing the need to redesign their networks because manufacturers will be able to use the rules adopted herein to design equipment that achieves link distances comparable to what they were able to achieve with the old rules. The Commission therefore adds new language for Section 15.407 (b)(4) that would provide relief from the OOBE limits adopted in the *First R&O* by permitting emissions to roll off linearly from 27 dBm/MHz at the band edge to a level of 15.6 dBm/MHz at 5 MHz from the band edge, then decreasing linearly to 10 dBm/MHz at 25 MHz from the band edge and continue to decrease linearly to a level of −27 dBm/MHz at all frequencies more than 75 MHz from band edge. The Commission adopts additional provisions in the first 5 MHz outside of the band edge because manufacturers have sufficiently demonstrated their inability to suppress their emissions to meet the Ubiquiti Proposal mask within this region. This approach will offer the needed relief to manufacturers, but will still provide a level of interference protection to adjacent band services that is greater than that provided in Section 15.247. This approach offers relief for users and manufacturers by relaxing the OOBE roll-off requirement outside of the TDWR band while maintaining the same level of interference protection within the TDWR band as specified under the rules the Commission adopted in the *First R&O.*

B. Association of Global Automakers Petition

9. Dedicated Short Range Communications (DSRC) Systems are designed to operate under the FCC provisions for the Intelligent Transportation Systems (ITS) radio service in the 5.85–5.925 GHz band. Prior to the adoption of the *First R&O,* unlicensed devices were permitted in the adjacent 5.725–5.85 GHz band under two different rules, Sections 15.247 and 15.407. The Commission, in the *First R&O,* consolidated the rules for devices operating in the 5.725–5.85 GHz band and imposed the more stringent Section 15.407 OOBE limits, which provide more protection from interference to adjacent band incumbent spectrum users.

10. In its petition for reconsideration, the Association of Global Automakers, Inc. (Global) requests that the Commission suspend or reverse key decisions made in the *First R&O* because it failed to explain how its decision to allow additional, higher-powered, unlicensed U–NII devices to operate in the 5 GHz band would not cause harmful interference to previously-authorized DSRC operations. It claims that substantial evidence suggests that harmful interference will likely result to DSRC operations from expanded "high power Wi-Fi" operations in the 5 GHz band. Global further states that the FCC should explain what steps the agency will take to protect DSRC operations against that

harmful interference; the Commission should adopt procedures that will swiftly and effectively resolve any harmful interference that may subsequently occur to DSRC from U–NII devices; and if the FCC expects that there will be some level of interference between these adjacent-band operations, the FCC should clarify what level of interference will be acceptable and what course of action will be available to DSRC operators to protect their networks from unacceptable levels of interference. The majority of parties that responded to Global's petition were opposed to reversing the decisions that the Commission made in the *First R&O* regarding the U–NII–3 band.

11. The Commission rejects Global's Request and declines to reverse or suspend its decision to consolidate the rules for unlicensed devices operating in the 5.725–5.85 GHz band under one rule section. The Commission finds that DSRC systems will receive greater interference protection under the emission mask adopted in this MO&O than was provided under the old rules. In the *First R&O* the Commission explained that higher powered operations in the 5.725- 5.85 GHz band are already permitted to operate under Section 15.247, and that adopting more stringent limits for the newly modified Section 15.407 rules would reduce the OOBE from each U–NII–3 device and, in turn, should reduce the aggregate emissions from these devices. Therefore, the decisions made in the *First R&O* with respect to U–NII–3 did not result in an expansion of use but, instead, provided increased protection for systems operating in the adjacent bands, such as DSRC systems and TDWRs. Even with the slight relaxation of the U–NII–3 OOBE limit that are being adopted in this MO&O, the allowed emissions from U–NII devices into the DSRC band will still be held to a lower limit than what was permitted by Section 15.247 prior to the adoption of the *First R&O*. This in turn will result in less potential interference to ITS operating in the adjacent band because the per device and aggregate emissions in the band will be reduced. Additionally, the Commission believes the additional level of protection afforded to DSRC systems is sufficient because, unlike the TDWR, the DSRC systems were not experiencing interference problems previously. Given that the new rules increase protections for the ITS systems, the Commission does not consider additional protections from adjacent band signals to be necessary.

C. EchoStar Proposal

12. Prior to adoption of the *First R&O*, the 5.15–5.25 GHz (U–NII–1) band had a very low peak transmitter conducted output power limit of 50 mW, and U–NII operations were restricted to indoor only operations. In the *First R&O*, the Commission adopted rules to remove the indoor-only restriction and increased the permitted power for these devices in order to increase the utility of the U–NII–1 band and to accommodate the next generation of Wi-Fi technology. Specifically, under the new rules all client devices in the U–NII–1 band may now operate at conducted power levels up to 250 mW without distinction as to whether devices are located indoors or outdoors. The new rules permit Access Points to operate in the U–NII–1 band at conducted power levels up to 1 Watt if they use antennas that limit gain in the upward direction, or if they are located indoors. Client devices are permitted to operate in the U–NII–1 band without limiting the antenna gain in the vertical direction because they typically represent mobile or portable devices, such as handsets, laptops, and tablets. These devices are not typically installed in permanent outdoor locations, and due to their mobile nature the antenna gain in any particular direction cannot be guaranteed. Finally, many client devices incorporate power control features that encourage the device to use as little power as necessary to establish and maintain the communications link. In consideration of all of these factors, the Commission anticipated a negligible interference potential associated with client devices that operate as described and, as a result, determined that the antenna requirements described above for access points were not necessary for client devices.

13. EchoStar (ETC) argues that the *First R&O* is unclear regarding the power limit applicable to its set-top boxes that serve as client devices for indoor wireless access points and operate in the U–NII–1 band (5.15–5.25 GHz). ETC further asks the Commission to permit such set-top boxes to operate at the maximum power level afforded under new Section 15.407(a)(1)(ii) (*i.e.*, 1 Watt). ETC states that it has integrated Wi-Fi technologies into its set-top boxes and systems to facilitate the distribution of programming within a customer location, at faster speeds than those achievable via in-home cable connections. By including an access point as part of the customer's installation, the system effectively creates a private Wi-Fi network in the home. ETC claims that it is essential that they be permitted to operate at the same maximum power levels that Part 15 affords to facilitate access points and other indoor devices that operate in an entirely stationary mode.

14. ETC stated in its petition that while these devices are not usually attached to anything physically, the box can only operate while sitting still and, generally cannot be moved throughout the home without risking a degradation or loss of video service. As such, the box is functionally identical to an indoor access point, and therefore, the interference considerations are the same for both. Thus, ETC claims there is no reason not to permit both types of devices to transmit at a maximum power level of 1 Watt when operating in the U–NII–1 band. Several parties supported ETC's request for a clarification of the rules.

15. The Commission clarifies that in the *First R&O* it adopted a power limit of 250 mW for all client devices, regardless of whether they are fixed, mobile, or portable. While the Commission noted that client devices are "typically mobile or portable," it also made clear that the new 250 mW power limit applies to "any client device which operates under control of an access point." To avoid further confusion, the Commission on reconsideration modifies Section 15.407(a)(1)(iv) by deleting the words "mobile and portable".

16. In response to ETC's recommendation to adopt rules that allow U–NII–1 band indoor set-top boxes or any other type of client devices to operate at 1 Watt, the same power levels as U–NII–1 band access points, the Commission declines to do so. As a point of clarification, the Commission has allowed set-top boxes that serve as access points to operate up to 1 Watt based on the rationale that access points generally remain in one location. However, it has treated client devices as subject to the 250 mW limit because it is generally more difficult to control the location and use of these devices (*i.e.*, client devices can be used outdoors). Some commenters have suggested that a possible point of distinction between fixed and mobile client devices could be the need for AC power. The Commission notes, however, that many mobile devices can operate from AC power as an alternative to battery power. While it understands from Echostar's petition that their particular set-top box is not designed to be moved throughout the home, the Commission is not convinced that this can be ensured on a general basis for all "fixed" client devices and there is no reliable way to determine whether or

not a client device will be positioned indoors or outdoors.

17. It is unclear from Echostar's petition that its set top box qualifies as an access point and therefore would be permitted to operate at 1 W. This will depend on the specific characteristics of the device as presented through the equipment authorization process. Echostar and any other entity can, therefore, seek approval, at the time it files for equipment authorization, for a set-top box or other such device to operate up to 1 Watt by making a showing that it serves as an access point. However, the Commission is not convinced of the need to increase the in-band power levels for set-top boxes, and if consumers desire to increase the range between the access point and the set-top boxes, repeaters are widely available at commercially reasonable prices for this purpose. The Commission concludes that 250 mW is adequate for most client device installations. For the aforementioned reasons, the Commission will continue to limit client devices in the U–NII–1 band to operating at conducted power levels up to 250 mW with a maximum PSD level of 11dBm/MHz using a transmit antenna with a maximum gain of 6 dBi. It continues to impose this limit on client devices, and without distinction as to whether devices are located indoors or outdoors.

D. Proposals To Increase OOBE in Restricted Bands 5.091–5.15 GHz

18. Section 15.205 identifies a number of restricted bands in which low power, non-licensed transmitters are not allowed to place any portion of their fundamental emission because of potential interference to sensitive radio communications such as commercial aviation communications and navigation, radio astronomy, search and rescue operations, and other critical government radio services. Additionally, unwanted emissions from non-licensed transmitters that fall into restricted bands must comply with the general radiated emission limits in Section 15.209. The 5.091–5.15 GHz band falls within the larger 4.5–5.15 GHz restricted band, as specified in Section 15.205(a).

19. The 5.091–5.15 GHz band is allocated to the Aeronautical Mobile Service (AMS) on a primary basis for Federal and non-Federal use, including aeronautical fixed communications; Aeronautical Mobile Telemetry (AMT), restricted to 52 designated flight test areas and additional locations authorized for flight testing on a case-by-case basis; and the Fixed Satellite Service (FSS) limited to feeder links for non-geostationary orbit (NGSO) satellite systems in the Mobile Satellite Service (MSS).

20. The Wireless Internet Service Provider Association (WISPA) et al. supports relaxing the Section 15.205 provisions between 5.091 GHz and 5.15 GHz by 1dB for every dB that the antenna gain exceeds 6 dBi, provided that the antenna is oriented at 30 degrees or less above the horizon. Fastback proposes to change the restricted band at 4.5–5.15 GHz to end at 5.091 GHz, thus allowing higher out of band emissions (up to –17 dBm/MHz) from U–NII–1 devices into the 5.091–5.15 GHz portion. It states that adopting its proposed recommendations would enable an increase in EIRP for U–NII–1 point-to-point links, corresponding to an increased communication range of two hundred and fifty percent.

21. The Commission declines to increase the allowable emissions from U–NII band devices into the restricted band below 5.15 GHz. The restricted bands were created to protect radio communications services that are sensitive to interference and that provide critical benefits to public safety and national security. WISPA and Fastback have not offered any analysis showing that increasing the emissions limit in this restricted band would not create an unacceptable risk of interference in the restricted band. Moreover, to the extent that WISPA and Fastback make their proposals in order to increase the utilization of the U–NII–1 band, the Commission observes that it other rule revisions adopted in this order accomplish this purpose, by removing the restriction to indoor operation and increasing the permitted power level for U–NII–1 devices. The emission limits into the adjacent restricted band from U–NII–1 devices may not provide all of the benefits that some equipment suppliers desire, and some equipment manufacturers may find that they need to reduce power below the level permitted under the rules in order to achieve compliance with the OOBE limit below 5.15 GHz. However, the removal of the indoor restriction and the increase in power permitted in the 5.15–5.25 GHz band provide greater opportunities than were available before. Other parts of the 5 GHz band can accommodate higher powered operation where it may not be possible to achieve the desired power level and compliance with the OOBE limit at 5.15—5.25 GHz.

E. Proposals To Extend the Transition Period

22. The Commission adopted rules requiring that, 12 months after the effective date of the *First R&O* (June 2, 2015), applications for certification of 5 GHz devices must meet the new and modified rules. Additionally, the Commission required that the manufacture, marketing, sale and importation into the United States of devices that did not meet the new or modified rules must cease two years after the effective date of the rules adopted in the *First R&O* (June 2, 2016). While the Commission was sympathetic to the arguments of commenters that the more restrictive unwanted emission limits for digital modulation devices may present design challenges for some manufacturers, the Commission ultimately found that it was in the public interest to implement the changes as soon as possible to eliminate the potential of harmful interference to TDWRs.

23. Motorola Solutions, Inc. (MSI) asks that the Commission reconsider its requirement that the manufacture, marketing, sale and importation into the United States of digitally modulated and hybrid devices certified under Section 15.247 cease operating in the 5.725–5.850 GHz U–NII–3 band two years after the effective date of the *First R&O*. MSI estimates that almost all of its nearly 200 enterprise WLAN products and access points will require reengineering to comply with the more stringent OOBE requirements and believes this undertaking cannot be completed in two years. MSI recommends a five-year transition, but they believe it is unnecessary and arbitrary to impose any time limit on the continued sale of pre-approved devices, as the new certification obligations adopted by the Commission will facilitate a prompt transition on their own. Similarly, Cambium requests that the one-year and two-year deadlines be extended to three years for equipment not yet certified and the two-year deadline be eliminated for product models certified under the old rules. They claim that this will allow manufacturers a reasonable timeframe to address design issues with meeting new requirements.

24. Cisco raises no objection to a short extension of the transition deadlines if manufacturers can make a compelling case that it is not possible to redesign and re-certify equipment with a reasonable effort, but given the central role U–NII–3 equipment has played in causing interference to TDWR, any extension that delays the introduction of enhanced security features should be as brief as possible. MSI clarifies that its petition was not intended to extend the deadline for introduction of enhanced security features to previously certified devices, but to limit the period of time

in which equipment previously certified under the legacy rules could continue to be manufactured and marketed. Broadcom claims that enterprise and home router devices that use its chipsets, which are generally operated indoors using a lower gain antenna, have less potential to cause interference than the point-to-point systems operating outdoors that are using high-gain antennas that prompted the industry emission limits proposal adopted in this proceeding. Broadcom states that although it would be able to meet the emission limits we adopted above, it would need more time to bring their devices into compliance.

25. The Commission modifies the dates by which the certification, manufacture, marketing, sale and importation into the United States of U–NII–3 band devices that do not meet the modified emission limits adopted in this Memorandum Opinion and Order must cease. The Commission modifies Section 15.407(b)(4) to permit manufacturers of devices certified before March 2, 2017 with antenna gain greater than 10 dBi to demonstrate compliance with the emission limits in Section 15.247(d), but manufacturing, marketing, sale and importing of devices certified under this alternative must cease by March 2, 2018. The Commission further modify Section 15.407(b)(4) to permit manufacturers of devices certified before March 2, 2018 with an antenna gain of 10 dBi or less to demonstrate compliance with the emission limits in Section 15.247(d), but manufacturing, marketing, sale and importing of devices certified under this alternative must cease before March 2, 2020. The Commission has already issued two orders that have provided a 10-month extension that permitted manufacturers to continue to certify devices under the old rules until March 2, 2016. Here, the Commission does not further extend the transition provisions in Section 15.37(h) allowing certification and marketing under the old rules, but rather implement a phased implementation of only the out-of-band limits in Section 15.407.

26. The Commission understands Cisco's concerns and agrees that manufacturers should be granted an extension of time only if they cannot comply with the modified rules with reasonable effort and that the time extension should not be indefinite. The Commission recognizes that during the years leading up to the rule change, the industry had made a significant investment in the research, design, and development of new product lines. The Commission also recognizes that manufacturers have made a significant effort to design compliant equipment but are not able to reasonably suppress their OOBEs without significantly reducing the in-band power and thereby reducing the range of their devices. The majority of products that are effected, operate with relatively low power and employ antenna gains of less than 10dBi. The Commission understands that the typical design cycle for enterprise and home routers can last two to three years and that there is no simple solution for manufacturers to swiftly redesign compliant products before the transition period deadlines. Therefore, the Commission will provide a slightly longer transition period for devices that operate a 10 dBi or lower antenna. The Commission notes that these devices tend to present a lower risk of harmful interference because they are typically lower powered and are installed indoor. The Commission recognizes that in theory, harmful interference could occur from an enterprise or home access point, however it has not observed this in practice. In practice, harmful interference to the TDWR was typically caused by long-range devices that were unlawfully modified and typically operated with antenna gains of 15 dBi and above. The devices that employ higher gain antennas are typically operated by service providers for the purposes of wireless back haul and are installed in outdoor environments. The Commission therefore concludes that in the case of devices that employ an antenna with a gain of 10 dBi or less, appropriate deadlines are March 2, 2018 for certification, and March 2, 2020 as the cut-off for devices that can be imported or marketed within the United States under the old emission limits.

27. The Commission believes these extensions will give manufacturers and vendors sufficient time to come into compliance with the new emission limits. The Commission does not believe a short extension of the deadlines will represent a significant risk of harmful interference for the TDWR. The new certification and marketing deadlines apply to devices that operate in the U–NII–3 band.

28. The Commission notes that the ultimate purpose of the transition date is to expediently reduce the threat of harmful interference to the TDWR and other radar facilities from devices on the market that were easily and unlawfully modified. However, the Commission recognizes that manufacturers will need additional time to design new product lines that comply with the new rules. Extending the emission limit deadlines will permit manufacturers to plan their research and design activities to comply with the outcome of our actions here. Permitting this extended period will provide economic relief by allowing manufacturers to continue to sell through remaining inventory. The Commission has already provided more time than originally intended to bring these devices into compliance and no further extensions are contemplated.

Procedural Matters

29. *Final Regulatory Flexibility Certification.* The Regulatory Flexibility Act of 1980, as amended (RFA)[1] requires that a regulatory flexibility analysis be prepared for notice-and-comment rule making proceedings, unless the agency certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." [2] The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." [3] In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act.[4] A "small business concern" is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the U.S. Small Business Administration (SBA).[5] The adopted rules pertain to manufacturers of unlicensed communications devices. The appropriate small business size standard is that which the SBA has established for radio and television broadcasting and wireless communications equipment manufacturing. The Census Bureau defines this category as follows: "This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers,

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[1] The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996).

[2] 5 U.S.C. 605(b).

[3] 5 U.S.C. 601(6).

[4] 5 U.S.C. 601(3) (incorporating by reference the definition of "small-business concern" in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies "unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register.**"

[5] 15 U.S.C. 632.

cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment."[6] The SBA has developed a small business size standard for firms in this category, which is: All such firms having 750 or fewer employees.[7] According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for part or all of the entire year. Of this total, 784 had fewer than 500 employees and 155 had more than 100 employees.[8] Thus, under this size standard, the majority of firms can be considered small.

30. Pursuant to the RFA, the Commission incorporated an Initial Regulatory Flexibility Analysis (IRFA) into the *Notice of Proposed Rulemaking (NPRM)* in ET Docket No. 13–49.[9] There were no public comments filed that specifically addressed the rules and policies proposed in the IRFA, and the Commission concluded in the Final Regulatory Flexibility Analysis (FRFA) in the *First Report and Order* (*First R&O*)[10] that the rules adopted in the *First R&O* do not add substantial additional compliance burden on small businesses. For the reasons described below, the Commission now certify that the policies and rules adopted in the present *Memorandum Opinion and Order* (*MO&O*) will not have a significant economic impact on a substantial number of small entities.

31. In the *First R&O,* the Commission prepared a FRFA detailing the ways in which the Commission sought to minimize the impact of the new regulations on small businesses.[11] The rule change adopted in this *MO&O* is merely a modification of the rule adopted in the *First R&O* that will provide relief for those entities that are required to comply with rules adopted in the *First R&O* and modified herein. Therefore, the Commission certify pursuant to the RFA that the final rule adopted in this order will not have a significant economic impact on a substantial number of small entities.[12]

32. The Commission will send a copy of the MO&O, including a copy of this final Regulatory Flexibility Certification,[13] in a report to Congress pursuant to the Congressional Review Act. In addition, the MO&O and this final certification will be sent to the Chief Counsel for Advocacy of the SBA, and will be published in the **Federal Register.**[14]

33. *Paperwork Reduction Act Analysis.* This document contains no new or modified information collection requirement that are subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. The Commission note that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, 44 U.S.C. 3506(c)(4), the Commission previously sought specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

34. *Congressional Review Act.* The Commission will send a copy of this Memorandum Opinion and Order in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

Ordering Clauses

35. Pursuant to Sections 4(i), 301, 302, 303(e), 303(f), 303(g), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302a, 303(e), 303(f), 303(g), and 303(r), this *Memorandum Opinion and Order* IS ADOPTED and Part 15 of the Commission's Rules, 47 CFR. Part 15, IS AMENDED. The revisions will be effective May 6, 2016 of this *Memorandum Opinion and Order.*

36. Pursuant to Sections 4(i), 302, 303(e) 303(f), 303(g), 303(r), and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 302, 303(e), 303(f), 303(g), 303(r), and 405, the petitions for reconsideration addressed ARE GRANTED, to the extent indicated above, and otherwise ARE DENIED.

37. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this *Memorandum Opinion and Order,* including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 15

Communications equipment.

Federal Communications Commission.
Marlene H. Dortch,
Secretary.

Final Rules

For the reasons discussed in the preamble the Federal Communications Commission amends 47 CFR part 15 as follows:

PART 15—RADIO FREQUENCY DEVICES

■ 1. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

■ 2. Section 15.407 is amended by revising paragraphs (a)(1)(iv) and (b)(4) to read as follows:

§ 15.407 General technical requirements.

(a) * * *

(1) * * *

(iv) For client devices in the 5.15–5.25 GHz band, the maximum conducted output power over the frequency band of operation shall not exceed 250 mW provided the maximum antenna gain does not exceed 6 dBi. In addition, the maximum power spectral density shall not exceed 11 dBm in any 1 megahertz band. If transmitting antennas of directional gain greater than 6 dBi are used, both the maximum conducted output power and the maximum power spectral density shall be reduced by the amount in dB that the directional gain of the antenna exceeds 6 dBi.

* * * * *

(b) * * *

(4) For transmitters operating in the 5.725–5.85 GHz band:

(i) All emissions shall be limited to a level of −27 dBm/MHz at 75 MHz or more above or below the band edge increasing linearly to 10 dBm/MHz at 25 MHz above or below the band edge, and from 25 MHz above or below the band edge increasing linearly to a level of 15.6 dBm/MHz at 5 MHz above or below the band edge, and from 5 MHz above or below the band edge increasing linearly to a level of 27 dBm/MHz at the band edge.

(ii) Devices certified before March 2, 2017 with antenna gain greater than 10 dBi may demonstrate compliance with the emission limits in § 15.247(d), but manufacturing, marketing and importing of devices certified under this alternative must cease by March 2, 2018. Devices certified before March 2, 2018 with antenna gain of 10 dBi or less may demonstrate compliance with the emission limits in § 15.247(d), but manufacturing, marketing and importing of devices certified under this alternative must cease before March 2, 2020.

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[6] U.S. Census Bureau, 2007 NAICS Definitions, "334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing"; *http://www.census.gov/naics/2007/def/ND334220.HTM#N334220.*

[7] 13 CFR 121.201, NAICS code 334220.

[8] *http://factfinder.census.gov/servlet/IBQTable?_bm=y&-fds_name=EC0700A1&-geo_id=&-_skip=300&-ds_name=EC0731SG2&-_lang=en.*

[9] *See Revision of Part 15 of the Commission's Rules to Permit Unlicensed National Information Infrastructure (U–NII) Devices in the 5 GHz Band* in ET Docket No. 13–40, *Notice of Proposed Rulemaking,* 28 FCC Rcd. 1769 (2013) (*NPRM*).

[10] *See Revision of Part 15 of the Commission's Rules to Permit Unlicensed National Information Infrastructure (U–NII) Devices in the 5GHZ Band,* ET Docket 13–49, 29 FCC Rcd 4127 (2014) (*First R&O*).

[11] *See First R&O* at 4165–4168.

[12] *See* 5 U.S.C. 605 (b).

[13] *See* 5 U.S.C. 801(a)(1)(A).

[14] *See* 5 U.S.C. 605(b).

* * * * *

[FR Doc. 2016–07847 Filed 4–5–16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2013–0121]

Federal Motor Vehicle Safety Standards; Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Denial of petitions for reconsideration.

SUMMARY: This document denies petitions for reconsideration submitted by bus manufacturers IC Bus, LLC (IC Bus), Daimler Trucks North America (Daimler Trucks) and Prevost, concerning a November 25, 2013 final rule requiring seat belts on large buses. IC Bus and Daimler Trucks petitioned to modify the definition of "over-the-road bus" specified in the final rule. NHTSA is denying these petitions because any change to the definition may serve to reduce the standard's applicability, contrary to Congressional and NHTSA intent, and the definition of "over-the-road bus" is sufficiently clear. Prevost petitioned to revise the seat belt anchorage strength requirements for last row seats having no passenger seating behind them. NHTSA is denying this petition primarily because the requested force level reduction may set strength levels below an acceptable level for a dynamic environment.

DATES: April 6, 2016.

FOR FURTHER INFORMATION CONTACT: *For non-legal issues:* Mr. Vinay Nagabhushana, Office of Crashworthiness Standards, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: (202) 366–1452. Facsimile: (202) 493–2739.

For legal issues: Ms. Deirdre Fujita, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Telephone: (202) 366–2992. Facsimile: (202) 366–3820.

SUPPLEMENTARY INFORMATION: This document denies petitions for reconsideration of a November 25, 2013 final rule requiring seat belts on large buses (78 FR 70416). We first deny the petitions submitted by bus manufacturers IC Bus and Daimler Trucks to modify the definition of "over-the-road bus" specified in the final rule. These petitions are denied because any change to the definition may serve to reduce the standard's applicability, contrary to Congressional intent and the safety need addressed by the rule, and the current definition of "over-the-road bus" is sufficiently clear as to which buses must be equipped with seat belts. Second, this document denies a petition for reconsideration from bus manufacturer Prevost to revise the seat belt anchorage strength requirements for last row seats having no passenger seating behind them. This petition is denied because, as explained in the 2013 final rule, the agency is concerned about the interchangeability of these seats with those equipped with integrated seat belts and the risk that a seat that is certified to a lesser requirement could be moved to a row that has passenger seats behind it. Further, we deny the petition because the requested force level reduction may set strength levels below an acceptable level for a dynamic environment.

I. Motorcoach Definition

On July 6, 2012, President Obama signed the "Moving Ahead for Progress in the 21st Century Act" (MAP–21), which incorporates the "Motorcoach Enhanced Safety Act of 2012" in subtitle G. Section 32703(a) of this legislation calls for prescribing regulations for seat belts at all designated seating positions in "motorcoaches." Section 32702(6) states that "[t]he term 'motorcoach' has the meaning given the term 'over-the-road bus' in section 3038(a)(3) of the Transportation Equity Act for the 21st Century (49 U.S.C. 5310 note)" with two specific exceptions.[1] Section 3038(a)(3) (49 U.S.C. 5310 note) defines the term "over-the-road bus" as a bus characterized by an elevated passenger deck located over a baggage compartment.[2]

On November 25, 2013, NHTSA issued a final rule on occupant protection in large buses, fulfilling the statutory mandate in section 32703(a) of MAP–21. The 2013 final rule amended Federal Motor Vehicle Safety Standard (FMVSS) No. 208, "Occupant crash protection," to require lap/shoulder seat belts for each passenger seating position in all new over-the road buses regardless of gross vehicle weight rating (GVWR). In the final rule, consistent with MAP–21, NHTSA incorporated the term "over-the-road bus" into FMVSS No. 208 and the definition for the term set forth in MAP–21. Further, finding a safety need to improve occupant protection for passengers on other large buses, the agency also required seat belts in new buses, other than over-the road buses, with a GVWR greater than 11,793 kilograms (kg) (26,000 pounds (lb)).[3]

Petitions for Reconsideration

In response to the November 25, 2013 final rule, the agency received petitions for reconsideration requesting the agency further define the term "over-the road bus" with dimensional specificity and/or with other bus attributes. IC Bus stated that the current definition of over-the-road bus is ambiguous and the terms "elevated passenger deck" and "baggage compartment" are undefined and subject to interpretation. IC Bus petitioned the agency to—

- modify the definition such that "over the road bus means a bus characterized by an elevated passenger deck to accommodate a baggage compartment underneath, except a school bus," and
- define the term "elevated passenger deck" based on physical attributes of the bus such as passenger compartment floor height as measured from the ground (scaled for different GVWR) or define a passenger compartment floor height requirement with respect to some specific vehicle reference point.

Daimler Trucks also petitioned the agency to modify the definition of over-the road bus to include objective dimensional criteria for the elevated passenger deck, such as floor height from the ground (variable for different GVWR), and also to define baggage compartment in terms of volume per seating position.

Agency Response

The petitioners did not provide information supporting the requested action. They made broad suggestions as to how the definition of over-the-road bus might be quantified, but specific criteria and supporting data were lacking in the submissions. The petitioners did not provide data on the floor height or luggage compartment volume for any bus body type. They did not discuss what floor height or luggage compartment volume should be used to distinguish an over-the-road bus from other buses, and the basis for the criterion.

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[1] The two exceptions are buses used for public transportation provided by, or on behalf of, a public transportation agency, and school buses.

[2] The definition also appears in 49 CFR 37.3.

[3] The exceptions in the final rule are non-over-the-road transit buses, school buses, prison buses and perimeter seating buses.

NHTSA has limited discretion regarding the "motorcoach" definition and the application of the November 2013 final rule. Section 32702(6) of MAP–21 precisely defines the meaning of the term "motorcoach," incorporating the "over-the-road bus" definition used in 49 U.S.C. 5310 note (which the petitioners seek to change). Further, section 32703(a) requires the Secretary to "prescribe regulations requiring safety belts to be installed in motorcoaches at each designated seating position." We note that buses are built for different purposes to different specifications, with varying floor height, floor length, compartment sizes, etc. Adding dimensional limits to the bus attributes as the petitioners suggest would reduce the number of vehicles fitting under the definition, which in turn would reduce the number of buses that would be required to have seat belts. The agency is concerned that such a reduction in the number of buses subject to the seat belt requirement would be contrary to Congress's intent to enhance the safety of buses used for passenger transport for compensation.[4] MAP–21 specified the over-the-road bus definition to be used by the agency, without regard to vehicle weight and without indicating any additional specificity in regards to floor height or luggage compartment volume.

Additionally, NHTSA does not believe that the requested action is needed to clarify the application of the seat belt requirement. The applicability of the requirement is quite clear. As previously discussed, all buses with a GVWR greater than 11,793 kg (26,000 lb) must have seat belts.[5] For buses with GVWRs of 11,793 kg (26,000 lb) or less, if the vehicle has "an elevated passenger deck located over a baggage compartment," it must have seat belts.

We believe that a bus manufacturer can determine whether the vehicle they manufacture must have seat belts, based on the vehicle's GVWR and whether the bus has a luggage compartment under any part of the passenger deck. A bus that does not fit the definition is one without a luggage-carrying compartment under any part of the passenger deck.

Based on the above, the agency declines the petitioners' request to modify the definition of over-the-road bus.

II. Reduced Anchorage Strength for Last Row Seats

As part of the motorcoach seat belt requirements, the agency specified that the seat belt assembly anchorages must meet the requirements of FMVSS No. 210, "Seat belt assembly anchorages," to ensure effective occupant restraint and to reduce the likelihood of their failure. Further, the rule required that the seat belt anchorages must be integrated to the seat structure, except for the belt anchorages in the last row of the coach (if there is no wheelchair position or side emergency door behind these seats) and in the driver seating position. For the excluded seats in the last row, the final rule provided manufacturers the option of either having an integrated seat belt or attaching the seat belt anchorages to the bus side or back structure, as such placement would not impede ingress or egress of passengers in the coach.

Petition for Reconsideration

In response to the final rule, Prevost petitioned asking for reduced "seat retention" requirements for last row seats where there is no possibility of any passengers being behind them. Prevost is concerned that "the very last seats are secured over a thin metal bulkhead which did not require being very rigid when there were no seat belts"[6] and believes that this bulkhead will require reinforcement. It claimed that "[a]ny strength requirement is transmitted into added weight which in turn transferred into fuel consumption." The petitioner argued that FMVSS No. 210 would be applicable to any other seats in the motorcoach where there would be combined belted occupant and inertial loading of the seat plus loading from the unbelted occupant behind, but for last row seats, there is no possibility of occupant loading from behind so the FMVSS No. 210 load should be reduced. No supporting data was provided in the petition.

Agency Response

The agency has carefully considered the petitioner's request to reduce the seat belt anchorage forces for the subject seats. We are denying the request for the reasons explained below.

We first note that Prevost's petition is essentially a repeat of the comments it made to the notice of proposed rulemaking (NPRM)[7] preceding the final rule. The agency responded to that comment in the preamble of the final rule as follows:

> We are unable to agree to Prevost's suggestion that the strength requirements be adjusted (reduced) for seats where there are no other seats behind it (and therefore no unbelted passengers seated behind it). We are aware that some operators of covered buses have changed the passenger seating configuration from that set by the factory or have removed and reinstalled seats. If "weaker" seats are moved after the factory installation to a position that had a passenger seat behind it, the weaker seat would not provide the performance required by FMVSS No. 210. Furthermore, this final rule provides some of the flexibility Prevost seeks. Under this final rule, seats with no other seats behind them are not required to have the lap/shoulder belt anchorages attached to the seat structure. For these seats, the lap/shoulder belt anchorages can be attached directly to the vehicle structure. (78 FR at 70455)

Consistent with our final rule response, we remain concerned about the interchangeability of the seats with integrated seat belts, particularly in consideration of the long life of these vehicles (20+ years) and subsequent sales to operators that may need to reconfigure seating. If the operator moved the reduced-strength seat to a position that had a passenger seat behind it, the moved seat will not have the characteristics needed to withstand the loading from the aft passengers. If the reduced-strength seat were in a position that had a storage space behind it, loose items may create forward loading in a crash, similarly to rear occupant loading. The petitioner did not address this point. Similarly, no information or analysis was provided to suggest a value by which the seat belt anchorage strength requirement should be reduced.

The agency is not convinced of the merits of lowering the strength requirement per se. NHTSA conducted a full scale 48 kilometers per hour (km/h) (30 miles per hour) crash test of a 2000 Model Year MCI 102EL3 Renaissance motorcoach (capacity of 54 passengers seats). Post-test examination of the bus[8] found shoulder belt D-ring excursion for one of the seats (seating position 11R). The top bolt of the D-ring shoulder belt mount attached to the seat back by two bolts sheared resulting in forward excursion of the D-ring. This was a row of 7G Amaya seats with two 50th percentile dummies restrained with lap/shoulder belts. There was no added reinforcement to the floor or to the side structure and no occupant loading from behind. This seat design passed the FMVSS No. 210 force requirements in our static pull tests. Although the D-ring mount failure did not result in dummy contact with the seats in front of them or result in high injury values, it suggests that the dynamic loading was sufficient to cause partial failure of the torso anchorage hardware without any loading from dummies in the row behind. Thus, the agency is concerned that any reduction in the seat belt loading below the FMVSS No. 210 level may reduce the torso anchorage strength to an unacceptable level.

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[4] Section 32702(7) of MAP–21 defines "motorcoach services" as "passenger transportation by motorcoach for compensation."

[5] See footnote 3, supra, for exceptions.

[6] Docket No. NHTSA–2013–0121–005.

[7] 75 FR 50958 (August 18, 2010).

[8] Figure 7 in Technical Report DOT HS 813 335, Docket NHTSA–2013–0121.

In addition, data indicate that the last row of seats may be subject to loading unique to the rear of the bus. The vehicle accelerometer data from the full scale crash test were suggestive of forward flexing and dynamic rebound near the rear wall of the passenger compartment, compared to the front of the passenger compartment.[9] The static FMVSS No. 210 test cannot account for the dynamic forward displacement and rebound of the vehicle structure to which the seat or seat belt may be anchored and any weakening of the attachments that may result from such dynamic phenomena. Thus, reducing the anchorage strength requirements for this last row of seats may set strength levels below an acceptable level for a dynamic environment.

In its petition, Prevost states that reducing the strength requirement of FMVSS No. 210 for last row seats would result in a weight reduction and fuel savings. The agency is not convinced that there would be a significant weight reduction or fuel savings. Prevost did not provide information substantiating its claims, such as data on the thickness changes to the metal bulkhead (for example) required to secure seat belts designed to comply with the FMVSS No. 210 requirements compared to current designs.

Further, the final rule permits—rather than requires—manufacturers to attach the seat belts to the vehicle structure for last-row seats. In the final rule, NHTSA stated that "[l]ap/shoulder belt equipped seats that meet the requirements of FMVSS No. 210 are available in the U.S. that are equivalent in weight to the European seats." (78 FR at 70460.) We concluded that, depending on the efficiency of the structural design, there would be little or no weight penalty associated with the structural changes needed to meet FMVSS No. 210. Thus, the petitioner could use the integrated seat belt design for the last row seats if attaching the belt to the bus rear wall is problematic. Regardless, we emphasize that the petitioners have not shown that there will be a weight penalty for seat belt anchorages integrated into the vehicle structure. The increased flexibility of attachment to the vehicle rather than the seat has expanded the opportunity for efficient, innovative and practicable designs for manufacturers choosing to attach the belts to the vehicle structure.

For the reasons stated above, NHTSA hereby denies all petitions for reconsideration of the November 25, 2013 final rule amending FMVSS No. 208.

Authority: 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.95.

Issued on: March 31, 2016.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2016–07828 Filed 4–5–16; 8:45 am]

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[9] The maximum dynamic deflection near the front of the passenger compartment was 1,727 mm (68 inches) and the maximum dynamic displacement near the rear wall was 1,930 mm (76 inches). The rear wall separates the engine compartment in large over-the-road buses and in other buses from the cargo compartment.

SURFACE TRANSPORTATION BOARD

49 CFR Part 1201

[Docket No. EP 720]

Accounting and Reporting of Business Combinations, Security Investments, Comprehensive Income, Derivative Instruments, and Hedging Activities

AGENCY: Surface Transportation Board.

ACTION: Final rule.

SUMMARY: The Surface Transportation Board (STB or Board) is adopting final rules that update the accounting and reporting requirements in its Uniform System of Accounts (USOA) for Class I Railroads so that they are more consistent with current generally accepted accounting principles (GAAP). The Board is also revising the schedules and instructions for the Annual Report for Class I Railroads (R–1 or Form R–1) to better meet regulatory requirements and industry needs.

DATES: This rule is effective on May 6, 2016.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245–0333. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Interstate Commerce Act, as amended by the ICC Termination Act of 1995 (ICCTA), Public Law 104–88, 109 Stat. 803, authorizes the Board, in 49 U.S.C. 11142, to prescribe a uniform accounting system for rail carriers subject to our jurisdiction and, in 49 U.S.C. 11161, to maintain cost accounting rules for rail carriers.[1] Sections 11142 and 11161 both require the Board to conform its accounting rules to GAAP "[t]o the maximum extent practicable." The USOA is set forth in the Board's regulations at 49 CFR part 1201—Subpart A. The USOA is used by the Class I Railroads[2] to comply with their statutory requirement to provide the Board an annual report, known as the R–1 report, that contains information about their finances and operating statistics. 49 U.S.C. 11145(b)(1) and 49 CFR 1241.11.

In a notice of proposed rulemaking served on July 8, 2015 (NPR), the Board proposed to make a number of changes to the USOA. First, the Board noted that the existing USOA does not specifically address the proper accounting and reporting for changes in the fair value of certain security investments, derivative instruments, and hedging activities, nor does it contain specific accounts to record amounts related to items of Other Comprehensive Income or provide a format to display comprehensive income in the Form R–1. Without specific instructions and accounts for recording and reporting these transactions and events, inconsistent and incomplete accounting would result. Thus, the Board proposed to amend its USOA and Form R–1 to account for those types of transactions and events. Specifically, the Board proposed updating the USOA to provide for: (1) Fair value presentation of certain security investments, derivative instruments, and hedging activities; and (2) presentation of comprehensive income and components of other comprehensive income.

The Board proposed these revisions based on the GAAP promulgated by the Financial Accounting Standards Board (FASB)[3] in the following Accounting

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[1] The Board has broad economic oversight of railroads, 49 U.S.C. 10101–11908, and prescribes a uniform accounting system for rail carriers to use for regulatory purposes, 49 U.S.C. 11141–43, 11161–64; 49 CFR parts 1200–1201. In addition, the Board requires Class I railroads to submit quarterly and annual reports containing financial and operating statistics, including employment and traffic data. 49 U.S.C. 11145; 49 CFR 1241–1246, 1248.

[2] The Board designates three classes of freight railroads based upon their operating revenues, for three consecutive years, in 1991 dollars, using the following scale: Class I—$250 million or more; Class II—less than $250 million but more than $20 million; and Class III—$20 million or less. These operating revenue thresholds are adjusted annually for inflation. 49 CFR pt. 1201, 1–1. Adjusted for inflation, the revenue threshold for a Class I rail carrier using 2014 data is $475,754,803. Today, there are seven Class I carriers.

[3] FASB is a private, non-profit organization responsible for setting accounting standards for public companies in the United States.

Standards Codifications (ASC): ASC 320 Investments—Debt and Equity Securities; ASC 220 Comprehensive Income; ASC 815 Derivatives and Hedging; and ASC 805 Business Combinations.[4] The Board stated that the purpose of the proposed revisions is to provide consistent accounting and reporting of changes in the fair value of security investments, derivative instruments, and hedging activities. The Board further stated that the proposed changes would minimize the accounting and reporting burden on railroads under the Board's jurisdiction, assist the Board in its overall monitoring effort, and improve transparency.

Second, the Board proposed revising the USOA to reflect current accounting practices for business combinations by removing existing instructions for the pooling-of-interest method of accounting and replacing those instructions with the acquisition accounting method. This method of accounting has been standard practice in the accounting industry for some time, and the Board has already agreed that the acquisition method better reflects the investment made in an acquired entity and has affirmed the use of this treatment.[5] Thus, in the NPR, the Board proposed to update the USOA to reflect this accounting treatment.

Finally, the Board proposed revising the Form R–1 to include new accounts and a new reporting schedule and eliminating 15 schedules that the Board no longer uses.

The proposed rules were published in the **Federal Register**, 80 FR 39,021 (July 8, 2015). The Board received comments from the Association of American Railroads (AAR); no reply comments were filed.

Final Rules

The Board has reviewed the issues raised in AAR's comments and addresses them below, along with any revisions made in response. The final rules in full are below.

Accounting and Reporting of Business Combinations, Security Investments, Comprehensive Income, Derivative Instruments, and Hedging Activities

In the NPR, the Board proposed to amend its USOA and Form R–1 by adding new general instructions and accounts to recognize changes in the fair value of certain security investments, items of other comprehensive income, derivative instruments, and hedging activities. Additionally, the Board proposed revising its USOA to reflect current accounting practices for business combinations by removing existing instructions for the pooling-of-interest method of accounting and requiring only the acquisition accounting methodology. The Board also sought comment on its proposal to revise the Form R–1 to include the new accounts and a new reporting schedule.

No comments were filed in opposition to these proposals. Thus, the Board adopts such proposals here in the final rules. These changes will improve completeness and consistency of accounting and reporting. The addition of the proposed new accounts and related reporting requirements to the Form R–1 will reduce regulatory uncertainty as to the proper accounting and reporting for these items and minimize regulatory burden by reducing the potential differences in the manner in which certain amounts are reported to shareholders and to the Board. Finally, the reporting of derivative instruments and hedging activities by regulated carriers will assist the Board in its overall monitoring effort as well as its ability to assess railroad industry growth and financial stability.

Elimination of, or Changes to, Certain Schedules

The Board stated in the NPR that it had examined the current Form R–1 and determined that 15 of the 47 schedules were no longer used by the Board to perform regulatory and oversight functions. The Board, therefore, proposed to eliminate the following 15 schedules:

230	Capital Stock
339	Accrued Liability—Leased Property
340	Depreciation Base and Rates—Improvements to Road and Equipment Leased from Others
350	Depreciation Base and Rates—Road and Equipment Leased to Others
351	Accumulated Depreciation—Road and Equipment Leased to Others
416	Supporting Schedule—Road
418	Supporting Schedule—Capital Leases
460	Items in Selected Income and Retained Earnings Accounts for the Year
702	Miles of Road at Close of Year—By States and Territories (Single Track)
721	Ties Laid in Replacement
722	Ties Laid in Additional Tracks and in New Lines and Extensions
723	Rails Laid in Replacement
724	Rails Laid in Additional Tracks and in New Lines and Extensions
725	Weight of Rail
726	Summary of Track Replacements

In its comments, AAR states that it supports the Board's proposal to eliminate these schedules from the Form R–1, with the exception of Schedule 702, Miles of Road at Close of Year-By States and Territories (Single Track). According to AAR, Schedule 702 should be retained because this schedule is used to calculate state tax rates in the Revenue Shortfall Allocation Method.[6]

We agree with AAR that Schedule 702 should be retained. The Form R–1 report, filed annually by Class I railroads, includes the mileage necessary to weight average state tax rates that are utilized in the Revenue Shortfall Allocation methodology.[7] Therefore, Schedule 702 will be retained.

In addition to the schedules proposed for elimination in the NPR, AAR requests, consistent with its comments previously filed in *Improving Regulation & Regulatory Review,* Docket No. EP 712, that the Board eliminate Schedule 220, Retained Earnings; Schedule 342, Accumulated Depreciation—Improvements to Road and Equipment Leased from Others; Schedule 501, Guarantees and Suretyships; and Schedule 502, Compensating Balances and Short-Term Borrowing Arrangements. AAR further requests that the Board eliminate Schedule 310, Investments and Advances Affiliated Companies and Schedule 310A, Investments in Common Stocks of Affiliated Companies. According to AAR, these schedules are unnecessary because they capture data that is neither used nor usable to support the Board's regulatory objectives.

The Board will not adopt AAR's proposals to eliminate these other schedules. Schedule 220, Retained Earnings, will be retained because it is a significant financial disclosure for stakeholders interested in changes in the retained earnings account during the reporting period and gives important insight into the rail carrier's financial performance. Schedule 342, Accumulated Depreciation—Improvements to Road and Equipment Leased from Others, will be retained because it is used in the Board's Uniform Rail Costing System (URCS) and review of depreciation studies. In addition, eliminating Schedule 342 would limit the Board's ability to collect sufficient detail for R–1 reporting regarding rail carriers' implementation of the updated GAAP standard for leases. Finally, Schedules 501 (Guarantees and Suretyships), 502 (Compensating Balances and Short-Term Borrowing Arrangements), 310 (Investments and Advances Affiliated Companies), and 310A (Investments in Common Stocks of Affiliated Companies), are currently used by the Board's Office of Economics in intercompany audits, as they provide detailed information related to the railroads' financial arrangements with affiliated companies and financial agreements with borrowers and lenders. Those schedules therefore will be retained.

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[4] These accounting pronouncements are available at *https://asc.fasb.org.*

[5] *See W. Coal Traffic League—Pet. for Declaratory Order,* FD 35506, slip op at 6–17 (STB served July 25, 2013).

[6] The Revenue Shortfall Allocation Method is one of the three benchmarks used to determine the reasonableness of a challenged rate under the Board's Three Benchmark methodology. *See Simplified Standards for Rail Rate Cases,* EP 646 (Sub-No. 1) (STB served Sept. 5, 2007); *Simplified Standards for Rail Rate Cases—Taxes in Revenue Shortfall Allocation Method,* EP 646 (Sub-No. 2) (STB served Nov. 21, 2008).

[7] *See Annual Submission of Tax Info. for Use in Revenue Shortfall Allocation Method,* EP 682, slip op. at 2 n.3 (STB served Feb. 26, 2010).

AAR further suggests, consistent with its comments in *Improving Regulation and Regulatory Review,* Docket No. EP 712, that the Board make certain changes to either conform Form R–1 schedules to GAAP or otherwise harmonize Form R–1 reporting requirements. In Schedule 210, Results of Operations, AAR suggests that the Board change the description in Line 41 from "Amortization of Discount on Funded Debt," to "Amortization of Premium or Discount on Funded Debt," to reflect that premium amortization is included in interest expenses. AAR also suggests removing Line 22 where amortization of premium on funded debt is currently reported. In Schedule 412, Way and Structures, AAR suggests adding a separate line for "Shop Machinery" to reconcile the amortization expenses and depreciation for road accounts required in Schedules 412 and 335, Accumulated Depreciation—Road and Equipment Owned and Used. For Schedule 415, Supporting Schedule—Equipment, AAR proposes that the Board combine owned and capitalized leases in the schedule and eliminate lines pertaining to "Machinery" because, according to AAR, this data is not in or supported by Schedule 410, Equipment Accounts. Finally, for Schedule 755, Railroad Operating Statistics, AAR suggests eliminating Line 89—Caboose Miles—due to the significant reduction in the use of cabooses by reporting rail carriers.

While the Board will not adopt AAR's suggestions that the Board make certain other changes to either conform Form R–1 schedules to GAAP or otherwise harmonize Form R–1 reporting requirements, the Board will provide clarifying instructions with respect to one of AAR's proposals.

First, we will not adopt AAR's requested changes to Schedule 210, Results of Operations. Although AAR's proposal would simplify the reporting presentation in the Form R–1, the Board's current practice of presenting premiums and discounts of funded debt separately is preferable because it allows for transparent financial reporting by showing both interest income and expense.

Additionally, AAR's suggestion that the Board combine owned and capitalized leases in Schedule 415 (Supporting Schedule—Equipment) will not be adopted because this change would limit the Board's ability to collect sufficient detail for R–1 reporting regarding railroads' implementation of the updated GAAP standards for leases. This change would also require a modification in how Schedule 415 is inputted in URCS. In addition, although AAR suggests that lines pertaining to "Machinery" be eliminated in Schedule 415 because, according to AAR, such data is not in or supported by Schedule 410 (Equipment Accounts), the Board will not do so because Schedule 415, Lines 38–40 reconcile to Schedule 410, Lines 203, 222, and 306.

In Schedule 755 (Railroad Operating Statistics), the Board will retain Line 89–Caboose Miles. While reporting carriers have been reducing the use of cabooses over time, a level of use still exists. Further, removing Line 89 would eliminate an operating statistic from the URCS calculation.

While AAR suggests adding a separate line for "Shop Machinery" in Schedule 412 (Way and Structures) to reconcile the amortization expenses and depreciation for road accounts required in Schedules 412 (Way and Structures) and 335 (Accumulated Depreciation—Road and Equipment Owned and Used), the Board notes that Schedule 412 reports a railroad's fixed roadway facilities; "Shop Machinery" does not fall into such a category, but should be recorded in equipment accounts. The Board, however, will clarify instruction 4 in Schedule 412 to read as follows: "Amortization adjustment of each road property type which is included in column (b) shall be repeated in column (d) as a debit or credit to the appropriate line item. The net adjustment on line 29 shall equal the adjustment reported on line 29 of Schedule 335, excluding Account 44, Shop Machinery."

In sum, the final rules will eliminate the schedules previously identified in the NPR except for Schedule 702, Miles of Road at Close of Year-By States and Territories (Single Track), as discussed above. The Board will also clarify R–1 Schedule 412 instruction 4 as it pertains to the treatment of Shop Machinery.

Instruction 2–15

As noted in the NPR, ASC 805 Business Combinations requires the use of the acquisition method of accounting for all business combinations. While this method of accounting has been standard practice in the accounting industry for some time, and the Board has already agreed that the acquisition method better reflects the investment made in an acquired entity and has affirmed the use of this treatment, the USOA has not been updated to incorporate the method.[8] Thus, the NPR proposed to update the USOA to reflect this accounting treatment.

In connection with that proposal, the Board specifically sought comment on the application of Instruction 2–15, paragraph (d) with respect to use of the pooling of interest method for transactions involving the acquisition and merger of property of subsidiaries in INSTRUCTIONS FOR PROPERTY ACCOUNTS. No comments were submitted regarding the treatment or application of Instruction 2–15, paragraph (d). Therefore, we will update Instruction 2–15, paragraph (d) to reflect the use of the acquisition accounting methodology and remove any reference or instruction pertaining to the pooling-of-interest methodology.[9]

ASC 410

In response to the NPR, AAR also suggests that the Board adopt ASC 410, Asset Retirement and Environmental Obligations, which addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. AAR, however, does not explain why it believes ASC 410 should be adopted. The Board has already determined in an Accounting Series Circular served on June 11, 2003, and sent to all accounting officers of Class I railroads, that the Board would not adopt Financial Accounting Standard (FAS) 143, Accounting for Asset Retirement

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[8] *See Western Coal Traffic League—Pet. for Declaratory Order,* FD 35506, slip op at 6–17.

[9] We believe that removing references or instructions pertaining to the pooling-of-interest methodology in Instruction 2–15, paragraph (d) directly follows from the NPR and the Board's adoption of the acquisition accounting methodology. It is also a logical outgrowth of the overall approach proposed in the NPR of shifting to the acquisition method of accounting for all business combinations. In proceedings governed by the rulemaking provisions of the Administrative Procedure Act, 5 U.S.C. 553, notice is sufficient if the final rule adopted by an agency is the logical outgrowth of the proposed rule on which it sought comment. *See EC–MAC Motor Carriers Serv. Ass'n,* SSM 118 (Sub-No. 2), slip op. at 3 (STB served Mar. 27, 2003) (citing *Fertilizer Inst.* v. *EPA,* 935 F.2d 1303, 1311 (D.C. Cir. 1991)).

Obligations, now codified as ASC 410, because to do so would be inconsistent with the Board's accounting rules.[10] Nothing in AAR's comments suggests any reason for altering the Board's 2003 determination. Accordingly, we will not adopt ASC 410 as suggested by AAR.

Periodic Review

As noted above, 49 U.S.C. 11142 and 11161 require the Board to conform its accounting rules to GAAP "[t]o the maximum extent practicable." Therefore, in keeping with this requirement, the Board will conduct a periodic review of its accounting standards not less than every five years.

Paperwork Reduction Act

In the NPR the Board sought comments pursuant to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501–3549, and Office of Management and Budget (OMB) regulations at 5 CFR 1320.11, regarding: (1) Whether the revisions to the collection of information proposed here are necessary for the proper performance of the functions of the Board, including whether the collection has practical utility; (2) the accuracy of the Board's burden assessment; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burdens of the collections of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate. Comments regarding the necessity, utility, and clarity of the information collection were received and are addressed above. No comments concerning the Board's burden estimates were received.

The proposed collection was submitted to OMB for review as required under the PRA, 44 U.S.C. 3507(d), and 5 CFR 1320.11. OMB withheld approval pending submission of the final rule. We are today submitting the collection contained in this final rule to OMB for approval. Once approval is received, we will post a copy of the revised Form R–1 on the Board's Web site. Unless renewed, OMB approval of this collection expires three years after the date that OMB approves the collection.

Regulatory Flexibility Act Statement

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, generally requires a description and analysis of new rules that would have a significant economic impact on a substantial number of small entities. In drafting a rule, an agency is required to: (1) Assess the effect that its regulation will have on small entities; (2) analyze effective alternatives that may minimize a regulation's impact; and (3) make the analysis available for public comment. 5 U.S.C. 601–604. Under § 605(b), an agency is not required to perform an initial or final regulatory flexibility analysis if it certifies that the proposed or final rules will not have a "significant impact on a substantial number of small entities."

Because the goal of the RFA is to reduce the cost to small entities of complying with federal regulations, the RFA requires an agency to perform a regulatory flexibility analysis of small entity impacts only when a rule directly regulates those entities. In other words, the impact must be a direct impact on small entities "whose conduct is circumscribed or mandated" by the proposed rule. *White Eagle Coop. Ass'n* v. *Conner,* 553 F.3d 467, 478, 480 (7th Cir. 2009). An agency has no obligation to conduct a small entity impact analysis of effects on entities that it does not regulate. *United Distrib. Cos.* v. *FERC,* 88 F.3d 1105, 1170 (D.C. Cir. 1996).

The rule changes adopted here will not have a significant economic impact upon a substantial number of small entities, within the meaning of the RFA. The reporting requirements are applicable only to entities that are required to file Form R–1 reports, *i.e.*, the Class I carriers. 49 CFR 1241.1. Class I carriers are large railroads; accordingly, there will be no impact on small railroads (small entities).[11] Therefore, the Board certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

Authority: 49 U.S.C. 11142 and 11164.

List of Subjects in 49 CFR Part 1201.

Railroads, Uniform System of Accounts.

It is ordered:

1. The final rules set forth below are adopted and will be effective on May 6, 2016. Notice of the rules adopted here will be published in the **Federal Register**.

2. This decision is effective on the date of service.

Decided: March 30, 2016.

By the Board, Chairman Elliott, Vice Chairman Miller, and Commissioner Begeman.

Tia Delano,

Clearance Clerk.

For the reasons set forth in the preamble, the Surface Transportation Board is amending part 1201 of title 49, chapter X, of the Code of Federal Regulations as follows:

PART 1201—RAILROAD COMPANIES

■ The authority citation for part 1201 continues to read as follows:

Authority: 49 U.S.C. 11142 and 11164.

Subpart A—Uniform System of Accounts

■ 2. Amend Regulations Prescribed by revising paragraph (ii), item 16(c), to read as follows:

List of Instructions and Accounts

REGULATIONS PRESCRIBED

* * * * *

(ii) * * *

16. * * *

(c) *Cost,* as applied to a marketable equity security, refers to the original cost as adjusted for unrealized holding gains and losses.

* * * * *

■ 3. Amend General Instructions by adding instructions 1–19 and 1–20, to read as follows:

GENERAL INSTRUCTIONS

* * * * *

1–19 *Accounting for Other Comprehensive Income.* (a) Railroads will record items of Other Comprehensive Income in account 799.1, *Other comprehensive income.* Amounts included in this account will be maintained by each category of Other Comprehensive Income. Examples of categories of Other Comprehensive Income include foreign currency items, minimum pension liability adjustments, unrealized gains and losses on available-for-sale type securities and cash-flow hedge amounts.

(b) Supporting records will be maintained for account 799 so that the company can readily identify the cumulative amount of Other Comprehensive Income for each item included in this account.

(c) When an item of Other Comprehensive Income enters into the determination of earnings in the current or subsequent periods, a reclassification adjustment will be recorded in account 799 to avoid double counting of when an item included in net income was also included in Other Comprehensive Income in the same or prior period.

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[10] Surface Transportation Board, Office of Economics, Environmental Analysis and Administration, Accounting Series Circular No. 202 (2003).

[11] Class I carriers generally do not fall under the definition of a "small rail carrier" as defined by the Small Business Administration (SBA). The SBA's Office of Size Standards has established a size standard for rail transportation, pursuant to which a "line-haul railroad" is considered small if its number of employees is 1,500 or less, and a "short line railroad" is considered small if its number of employees is 500 or less. 13 CFR 121.201 (industry subsector 482).

1–20 *Accounting for derivative instruments and hedging activities.* (a) A carrier will recognize derivative instruments as either assets or liabilities in the financial statements and measure those instruments at fair value. A derivative instrument is a financial instrument or other contract with all three of the following characteristics:

(1) The derivative instrument has one or more underlyings and a notional amount or payment provision. Those terms determine the amount of the settlement or settlements, and, in some cases, whether or not a settlement is required.

(2) The derivative instrument requires no initial net investment or an initial net investment that is smaller than would be required for other types of contracts that would be expected to have similar responses to changes in market factors.

(3) The derivative instrument's terms require or permit net settlement; the derivative instrument can readily be settled net by a means outside the contract; or the derivative instrument's terms provide for delivery of an asset that puts the recipient in a position not substantially different from net settlement.

(b) The accounting for the changes in the fair value of derivative instruments depends upon their intended use and designation. Changes in the fair value of derivative instruments not designated as fair value or cash flow hedges will be recorded in account 713.5, *Derivative instrument assets,* or account 763.5, *Derivative instrument liabilities,* as appropriate, with the gains or losses charged to earnings in account 551, *Miscellaneous income charges.*

(c) A derivative instrument may be specifically designated as a fair-value or cash-flow hedge. A hedge may be used to manage risk to price, interest rates, or foreign currency transactions. An entity will maintain documentation of the hedge relationship at the inception of the hedge that details the risk management objective and strategy for undertaking the hedge, the nature of the risk being hedged, and how hedge effectiveness will be determined.

(d) If the carrier designates the derivative instrument as a fair-value hedge against exposure to changes in the fair value of a recognized asset, liability, or a firm commitment, it will record the change in fair value of the derivative instrument designated as a fair-value hedge to account 713.6, *Derivative instruments assets—hedges,* or account 763.6, *Derivative instrument liabilities—hedges,* as appropriate, with a corresponding adjustment to the sub-account of the item being hedged. The ineffective portion of the hedge transaction will be reflected in the same income or expense account that would have been used if the hedged item had been disposed of or settled. In the case of a fair-value hedge of a firm commitment, a new asset or liability is created. As a result of the hedge relationship, the new asset or liability will become part of the carrying amount of the item being hedged.

(e) If the carrier designates the derivative instrument as a cash-flow hedge against exposure to variable cash flows of a probable forecasted transaction, it will record changes in the fair value of the derivative instrument in account 713.6, *Derivative instrument assets—hedges,* or account 763.6, *Derivative instrument liabilities—hedges,* as appropriate, with a corresponding amount in account 799.1, *Other comprehensive income,* for the effective portion of the hedge. The ineffective portion of the hedge transaction will be reflected in the same income or expense account that would have been used if the hedged item had been disposed of or settled. Amounts recorded in Other Comprehensive Income will be reclassified into earnings in the same period or periods that the hedged forecasted item affects earnings.

■ 4. Amend Instructions For Property Accounts by:

■ a. Revising paragraph (a) in Instruction 2–15;

■ b. Removing paragraph (b) in Instruction 2–15;

■ c. Redesignating paragraph (c) as paragraph (b) in Instruction 2–15;

■ d. Revising the newly designated paragraph (b) in Instruction 2–15;

■ e. Redesignating paragraph (d) as paragraph (c) in Instruction 2–15; and

■ f. Revising the newly designated paragraph (c) in Instruction 2–15.

The revisions read as follows:

INSTRUCTIONS FOR PROPERTY ACCOUNTS

* * * * *

2–15 * * * (a) When a railway or portion thereof constituting an operating unit or system is acquired in a business combination, that business combination shall be recorded in the accounts in the manner stated hereunder.

(b) Purchase:

(1) The amount includable in account 731, Road and equipment property, shall be the cost at the date of acquisition to the purchaser of the transportation property acquired. The cost assigned the property, as well as other assets acquired, shall be the amount of the cost consideration given. Where property and other assets are acquired for other than cash, including liabilities assumed and shares of stock issued, cost shall be determined by either the fair value of the consideration given or the fair value of the assets acquired, whichever is more clearly evident. In addition to any liabilities assumed, provision shall be made for such estimated liabilities as may be necessary.

(2) When the costs of individual units or classes of transportation property are not specified in the agreement, the cost assigned such property shall be apportioned among the appropriate primary accounts using the percentage relationship between the fair values for each class of property acquired and the total of such values.

(c) Merger of subsidiaries:

The acquisition and merger of property of subsidiaries controlled through ownership of the majority shares of voting stock is to be accounted for using the acquisition accounting methodology.

■ 5. Amend Instructions For Income And Balance Sheet Accounts by revising Instruction 5–2, paragraph (a), items (2), (3), and (4) to read as follows:

INSTRUCTIONS FOR INCOME AND BALANCE SHEET ACCOUNTS

* * * * *

5–2 * * *

(a) * * *

(2) Account 702, *Temporary cash investments,* account 721, *Investments and advances; affiliated companies,* and account 722, *Other investments and advances,* shall be maintained in such a manner as to reflect the marketable equity portion (see definition 26) and other securities or investments.

(3) For the purpose of determining net ledger value, the marketable equity securities in account 702 shall be considered the current portfolio and the marketable equity securities in accounts 721 and 722 (combined) shall be considered the noncurrent portfolio.

(4) Carriers will categorize their security investments as held-to-maturity, trading, or available-for-sale. Unrealized holding gains and losses on trading type investment securities will be recorded in account 551, *Miscellaneous income charges.* Unrealized holding gains and losses on available-for-sale type investment securities will be recorded in account 799.1, *Other comprehensive income.*

* * * * *

■ 6. Amend Income Accounts—Ordinary Items by adding a sentence at the end of the list of inclusions for account 551 "Miscellaneous income charges," paragraph (a) to read as follows:

INCOME ACCOUNTS

Ordinary Items

* * * * *

551 Miscellaneous income charges.

(a) * * *

Unrealized holding gains and losses on trading type investment securities.

* * * * *

■ 7. Amend General Balance Sheet Accounts Explanations—Assets, Current Assets by:

■ a. Adding a sentence to the end of the first paragraph in account 702 "Temporary cash investment";

■ b. Adding accounts 713.5 "Derivative instrument assets" and 713.6 "Derivative instrument assets–hedges."

The additions read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Current Assets

* * * * *

702 Temporary cash investments.

* * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

* * * * *

713.5 Derivative instrument assets.

This account shall include the amounts paid for derivative instruments, and the change in the fair value of all derivative instrument assets not designated as cash-flow or fair-value hedges. Account 551, *Miscellaneous income charges,* will be charged with the corresponding amount of the change in the fair value of the derivative instrument.

713.6 Derivative instrument assets—hedges.

(a) This account shall include the amounts paid for derivative instruments, and the change in the fair value of derivative instrument assets designated by the carrier as cash-flow or fair-value hedges.

(b) When a carrier designates a derivative instrument asset as a cash-flow hedge, it will record the change in the fair value of the derivative instrument in this account with a concurrent charge to account 799.1, *Other comprehensive income,* with the effective portion of the derivative's gain or loss. The ineffective portion of the cash-flow hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

(c) When a carrier designates a derivative instrument as a fair-value hedge, it will record the change in the fair value of the derivative instrument in this account with a concurrent charge to a sub-account of the asset or liability that carries the item being hedged. The ineffective portion of the fair-value hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

* * * * *

■ 8. Amend General Balance Sheet Accounts Explanations—Assets, Special Funds by:

■ a. In account 715 "Sinking funds," adding two sentences to the end of paragraph (b);

■ b. In account 716 "Capital funds," adding a sentence to the end of paragraph (a); and

■ c. In account 717 "Other funds," adding Note E.

The additions read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Special Funds

715 Sinking funds.

* * * * *

(b) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments. The cash value of life insurance policies on the lives of employees and officers to the extent that the carrier is the beneficiary of such policies shall also be included in this account.

* * * * *

716 Capital funds.

(a) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

* * * * *

717 Other funds.

* * * * *

Note E: This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments.

■ 9. Amend General Balance Sheet Accounts Explanations—Assets, Investments by:

■ a. In account 722 "Other investments and advances," adding two sentences to the end of paragraph (a); and

■ b. Removing account 724 "Allowance for net unrealized loss on noncurrent marketable equity securities—Cr."

The addition reads as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Assets

Investments

* * * * *

722 Other investments and advances.

(a) * * * This account shall also include unrealized holding gains and losses on trading and available-for-sale types of security investments. Include also the offsetting entry to the recording of amortization of discount or premium on interest bearing investments.

* * * * *

■ 10. Amend General Balance Sheet Accounts Explanations—Liabilities and Shareholders' Equity, Current Liabilities by adding accounts 763.5 "Derivative instrument liabilities" and 763.6 "Derivative instrument liabilities–hedges", to read as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Liabilities and Shareholders' Equity

Current Liabilities

* * * * *

763.5 Derivative instrument liabilities.

This account shall include the change in the fair value of all derivative instrument liabilities not designated as cash-flow or fair-value hedges. Account 551, *Miscellaneous income charges,* will be charged with the corresponding amount of the change in the fair value of the derivative instrument.

763.6 Derivative instrument liabilities—hedges.

(a) This account shall include the change in the fair value of derivative instrument liabilities designated by the carrier as cash-flow or fair-value hedges.

(b) A carrier will record the change in the fair value of a derivative instrument liability related to a cash-flow hedge in this account, with a concurrent charge to account 799.1, *Other comprehensive income,* with the effective portion of the derivative instrument's gain or loss. The ineffective portion of the cash-flow hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

(c) A carrier will record the change in the fair value of a derivative instrument liability related to a fair-value hedge in this account, with a concurrent charge to a sub-account of the asset or liability that carries the item being hedged. The ineffective portion of the fair-value hedge will be charged to the same income or expense account that would have been used if the hedged item had been disposed of or otherwise settled.

* * * * *

■ 11. Amend General Balance Sheet Accounts Explanations—Liabilities and Shareholders' Equity, Shareholders' Equity by:

■ a. Removing account 798.1 "Net unrealized loss on noncurrent marketable securities"; and

■ b. Adding account 799 "Accumulated Other Comprehensive Income."

The addition reads as follows:

GENERAL BALANCE SHEET ACCOUNTS EXPLANATIONS

Liabilities and Shareholders' Equity

Shareholders' Equity

* * * * *

799 Accumulated Other Comprehensive Income.

(a) This account shall include revenues, expenses, gains, and losses that are properly includable in Other Comprehensive Income during the period. Examples of items of Other Comprehensive Income include foreign currency items, minimum pension liability adjustments, unrealized gains and losses on certain investments in debt and equity securities, and cash-flow hedges. Records supporting the entries to this account shall be maintained so that the carrier can furnish the amount of Other Comprehensive Income for each item included in this account.

(b) This account shall also be debited or credited, as appropriate, with amounts of accumulated Other Comprehensive Income that have been included in the determination of net income during the period and in accumulated Other Comprehensive Income in prior periods. Separate records for each category of items will be maintained to identify the amount of the reclassification adjustments from accumulated Other Comprehensive Income to earnings made during the period.

■ 12. Revise Form of General Balance Sheet Statement to read as follows:

Form of General Balance Sheet Statement

The classified form of general balance sheet statement is designed to show the financial condition of the accounting company at any specified date.

ASSETS

- Current assets:
  - 701. Cash.
  - 702. Temporary cash investments.
  - 703. Special deposits.
  - 704. Loans and notes receivable.
  - 705. Accounts receivable; Interline and other balances.
  - 706. Accounts receivable; Customers.
  - 707. Accounts receivable; Other.
  - 708. Interest and dividends receivable.
  - 708.5. Receivables from affiliated companies.
  - 709. Accrued accounts receivable.
  - 709.5. Allowance for uncollectible accounts.
    - Net receivables.
  - 710. Working funds.
  - 711. Prepayments.
  - 712. Material and supplies.
  - 713. Other current assets.
  - 713.5 Derivative instrument assets.
  - 713.6 Derivative instrument assets-hedges.
  - 714. Deferred income tax debits.
    - Total current assets.
- Special funds:
  - 715. Sinking funds.
  - 716. Capital funds.
  - 717. Other funds.
    - Total special funds.
- Investments:
  - 721. Investments and advances; affiliated companies.
- Undistributed earnings from certain investments in account 751.
  - 721.5. Adjustments; investments and advances—affiliated companies.
- Net—investments and advances—affiliated companies.
  - 722. Other investments and advances.
  - 723. Adjustments; Other investments and advances.
  - Net—other investments and advances.
  - Total investments.
- Tangible property:
  - 731. Road and equipment property.
  - 735. Accumulated depreciation; Road and equipment property.
  - 736. Accumulated amortization; Road and equipment property—Defense projects.
  - Net road and equipment property.
  - 732. Improvements on leased property.
  - 733. Accumulated depreciation; Improvements on leased property.
  - 734. Accumulated amortization; Improvements on leased property—Defense projects.
  - Net improvements on leased property.
  - Total carrier property.
  - 737. Property used in other than carrier operations.
  - 738. Accumulated depreciation; Property used in other than carrier operations.
  - Net—property used in other than carrier operations.
  - Total tangible property.
- Intangible property:
  - 739. Organization expenses.
- Other assets and deferred debits:
  - 741. Other assets.
  - 743. Other deferred debits.
  - 744. Accumulated deferred income tax debits.
    - Total other assets and deferred debits.
    - Total assets.

Liabilities and Shareholders' Equity

- Current liabilities:
  - 751. Loans and notes payable.
  - 752. Accounts payable; Interline and other balances.
  - 753. Audited accounts and wages payable.
  - 754. Accounts payable; Other.
  - 755. Interest payable.
  - 756. Dividends payable.
  - 757. Payables to affiliated companies.
  - 759. Accrued accounts payable.
  - 760. Federal income taxes accrued.
  - 761. State and other income taxes accrued.
  - 761.5. Other taxes accrued.
  - 762. Deferred income tax credits.
  - 763. Other current liabilities.
  - 763.5 Derivative instrument liabilities.
  - 763.6 Derivative instrument liabilities—hedges.
  - 764. Equipment obligations and other long-term debt due within one year.
    - Total current liabilities.
- Long-term debt due after one year: [1]
  - 765. Funded debt unmatured.
  - 766. Equipment obligations.
  - 766.5. Capitalized lease obligations.
  - 767. Receivers' and trustees' securities.
  - 768. Debt in default.
  - 769. Accounts payable; Affiliated companies.
  - 770.1 Unamortized debt discount.
  - 770.2 Unamortized premium on debt.
    - Total long-term debt due after one year.
- Other long-term liabilities:
  - 771. Accrued liability; Pension and welfare.
  - 772. Accrued liability; Leased property.
  - 774. Accrued liability; Casualty and other claims.
  - 775. Other accrued liabilities.
  - 781. Interest in default.
  - 782. Other liabilities.
    - Total other long-term liabilities.
- Deferred credits:
  - 783. Deferred revenues—transfers from government authorities.
  - 784. Other deferred credits.
  - 786. Accumulated deferred income tax credits.
    - Total deferred credits.
- Shareholders' equity:
  - Capital stock:
    - 791. Capital stock.
    - 792. Liability for conversion of capital stock.
    - 793. Discount on capital stock.
      - Total capital stock.
  - Additional capital:
    - 794. Premiums and assessments on capital stock.
    - 795. Other capital.
      - Total additional capital.
- Retained earnings:
  - 797. Retained earnings; Appropriated.
  - 798. Retained earnings; Unappropriated.
    - Total retained earnings.
  - 798.5 Treasury stock.
  - 799. Accumulated Other Comprehensive Income.

ASSETS—Continued

Total shareholders' equity.
Total liabilities and shareholders' equity.

[1] To be divided as to "Total issued" and "Held by or for company."

■ 13. Amend Conversion Tables by revising General Balance Sheet Accounts Conversion Table to read as follows:

CONVERSION TABLES

* * * * *

GENERAL BALANCE SHEET ACCOUNTS CONVERSION TABLE

System of accounts eff. prior to April 2016		System of accounts eff. April 2016	
Account title	No.	No.	Account title
Cash	701	701	Cash.
Temporary cash investments	702	702	Temporary cash investments.
Special deposits	703	703	Special deposits.
Loans and notes receivable	704	704	Loans and notes receivable.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Traffic, car service and other balances—dr	705	705	Accounts receivable; interline and other balances.
		709.5	Allowances for uncollectible accounts.
		752	Accounts payable; interline and other balances.
Net balance receivable from agents and conductors	706	706	Accounts receivable; customers.
Miscellaneous accounts receivable	707	707	Accounts receivable; other.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Interest and dividends receivable	708	708	Interest and dividends receivable.
		708.5	Receivables from affiliated companies.
		709.5	Allowance for uncollectible accounts.
Accrued accounts receivable	709	709	Accrued accounts receivable.
Working fund advances	710	710	Working funds.
Prepayments	711	711	Prepayments.
Material and supplies	712	712	Material and supplies.
Other current assets	713	713	Other current assets.
		713.5	Derivative instrument assets.
		713.6	Derivative instrument assets—hedges.
Deferred income tax charges	714	714	Deferred income tax debits.
Sinking funds	715	715	Sinking funds.
Capital and other reserve funds	716	716	Capital funds.
Insurance and other funds	717	717	Other funds.
Investment in affiliated companies	721	721	Investments and advances; affiliated companies.
Other investments	722	722	Other investments and advances.
Reserve for adjustment of investment in securities—cr	723	721.5	Adjustments; investments and advances—affiliated companies.
		723	Adjustments; other investments and advances.
Road and equipment property	731	731	Road and equipment property.
Organization expenses	71	739	Organization expenses.
Improvements on leased property	732	732	Improvements on leased property.
Accrued depreciation; improvements on leased property.	733	733	Accumulated depreciation; improvements on leased property.
Accrued depreciation; road and equipment	735	735	Accumulated depreciation; road and equipment property.
Amortization of defense projects; road and equipment	736	736	Accumulated amortization; road and equipment property—defense projects.
		734	Accumulated amortization; improvements on leased property—defense projects.
Miscellaneous physical property	737	737	Property used in other than carrier operations.
Accrued depreciation; miscellaneous physical property.	738	738	Accumulated depreciation; property used in other than carrier operations.
Other assets	741	741	Other assets.
Unamortized discount on long-term debt	770.1	770.1	Unamortized debt discount.
Other deferred charges	743	743	Other deferred debits.
Accumulated deferred income tax charges	744	744	Accumulated deferred income tax debits.
Liabilities			
Loans and notes payable	751	751	Loans and notes payable.
		757	Payables to affiliated companies.
Traffic, car service and other balances—cr	752	752	Accounts payable; interline and other balances.
		705	Accounts receivable; interline and other balances.
		709.5	Allowance for uncollectible accounts.
Audited accounts and wages payable	753	753	Audited accounts and wages payable.
Miscellaneous accounts payable	754	754	Accounts payable; other.
		757	Payables to affiliated companies.

GENERAL BALANCE SHEET ACCOUNTS CONVERSION TABLE—Continued

System of accounts eff. prior to April 2016		System of accounts eff. April 2016	
Account title	No.	No.	Account title
Interest matured unpaid	755	755	Interest payable.
		757	Payables to affiliated companies.
Dividends matured unpaid	756	756	Dividends payable.
		757	Payables to affiliated companies.
Unmatured interest accrued	757	755	Interest payable.
		757	Payables to affiliated companies.
Unmatured dividends declared	758	756	Dividends payable.
		757	Payables to affiliated companies.
Accrued accounts payable	759	759	Accrued accounts payable.
Federal income taxes accrued	760	760	Federal income taxes accrued.
Other taxes accrued	761	711	Prepayments.
		761	State and other income taxes accrued.
		761.5	Other taxes accrued.
Deferred income tax credits	762	762	Deferred income tax credits.
Other current liabilities	763	763	Other current liabilities.
		763.5	Derivative instrument liabilities
		763.6	Derivative instrument liabilities—hedges
Equipment obligations and other debt due within one year.	764	764	Equipment obligations and other long-term debt due within 1 year.
Funded debt unmatured	765	765	Funded debt unmatured.
Equipment obligations	766	766	Equipment obligations.
Capitalized lease obligations	766.5	766.5	Capitalized lease obligations.
Receivers' and trustees' securities	767	767	Receivers' and trustees' securities.
Debt in default	768	768	Debt in default.
Amounts payable to affiliated companies	769	769	Accounts payable; affiliated companies.
Pension and welfare reserves	771	771	Accrued liability; pension and welfare.
Casualty and other reserves	774	774	Accrued liability; casualty and other claims.
		775	Other accrued liabilities.
Interest in default	781	781	Interest in default.
Other liabilities	782	782	Other liabilities.
Deferred revenues—transfers from government authorities..	783	783	Deferred revenues—transfers from government authorities
Unamortized premium on long-term debt	790.2	770.2	Unamortized premium on debt.
Other deferred credits	784	784	Other deferred credits.
Accrued liability; leased property	785	772	Accrued liability; leased property.
Accumulated deferred income tax credits	786	786	Accumulated deferred income tax credits.
Shareholders' Equity			
Capital stock issued	791	791	Capital stock.
Stock liability for conversion	792	792	Liability for conversion of capital stock.
Discount on capital stock	793	793	Discount on capital stock.
Premiums and assessment on capital stock	794	794	Premiums and assessments on capital stock.
Paid-in surplus	795	795	Other capital.
Other capital surplus	796	795	Do.
Retained income; appropriated	797	797	Retained earnings; appropriated.
Retained income; unappropriated	798	798	Retained earnings; unappropriated.
Treasury stock	798.5	798.5	Treasury stock.
		799	Accumulated Other Comprehensive Income.

Note: The following appendix will not appear in the Code of Federal Regulations.

BILLING CODE 4915–01–P

Appendix A

Road Initials: **Year:** **5**

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION – ASSETS

(Dollars in Thousands)

Line No.	Cross Check	Account	Title (a)	Balance at close of year (b)	Balance at beginning of year (c)	Line No.
			Current Assets			
1		701	Cash			1
2		702	Temporary cash investments			2
3		703	Special deposits			3
			Accounts receivable			
4		704	- Loan and notes			4
5		705	- Interline and other balances			5
6		706	- Customers			6
7		707	- Other			7
8		709, 708	- Accrued accounts receivables			8
9		708.5	- Receivables from affiliated companies			9
10		709.5	- Less: Allowance for uncollectible accounts			10
11		710, 711, 714	Working funds prepayments deferred income tax debits			11
12		712	Materials and supplies			12
13		713, 713.5, 713.6	Other current assets			13
14			TOTAL CURRENT ASSETS			14
			Other Assets			
15		715, 716, 717	Special funds			15
16		721, 721.5	Investments and advances affiliated companies			16
			(Schs. 310 and 310A)			
17		722, 723	Other investments and advances			17
18		737, 738	Property used in other than carrier operation			18
			(Less depreciation) $			
19		739, 741	Other assets			19
20		743	Other deferred debits			20
21		744	Accumulated deferred income tax debits			21
22			TOTAL OTHER ASSETS			22
			Road and Equipment			
23		731, 732	Road (Sch. 330) L-30 Col h & b			23
24		731, 732	Equipment (Sch 330) L-39 Col h & b			24
25		731, 732	Unallocated items			25
26		733, 735	Accumulated depreciation and amortization			26
			(Schs. 335, 342)			
27			Net Road and Equipment			27
28	*		Total Assets			28

NOTES AND REMARKS

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6 **Road Initials:** **Year:**

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - LIABILITIES AND SHAREHOLDERS' EQUITY

(Dollars in Thousands)

Line No.	Cross Check	Account	Title (a)	Balance at close of year (b)	Balance at beginning of year (c)	Line No.
			Current Liabilities			
30		751	Loans and notes payable			30
31		752	Accounts payable: interline and other balances			31
32		753	Audited accounts and wages			32
33		754	Other accounts payable			33
34		755, 756	Interest and dividends payable			34
35		757	Payables to affiliated companies			35
36		759	Accrued accounts payable			36
37		760, 761, 761.5	Taxes accrued			37
		762				
38		763, 763.5, 763.6	Other current liabilities			38
39		764	Equipment obligations and other long-term debt due within one year			39
40			TOTAL CURRENT LIABILITIES			40
			Non-Current Liabilities			
41		765, 767	Funded debt unmatured			41
42		766	Equipment obligations			42
43		766.5	Capitalized lease obligations			43
44		768	Debt in default			44
45		769	Accounts payable: affiliated companies			45
46		770.1, 770.2	Unamortized debt premium			46
47		781	Interest in default			47
48		783	Deferred revenues - transfers from govt. authorities			48
49		786	Accumulated deferred income tax credits			49
50		771, 772, 774,	Other long-term liabilities and deferred credits			50
		775, 782, 784				
51			TOTAL NON-CURRENT LIABILITIES			51
			Shareholders' Equity			
52		791, 792	Total capital stock			52
53			Common stock			53
54			Preferred stock			54
55			Discount on capital stock			55
56		794, 795	Additional capital			56
			Retained earnings:			
57		797	Appropriated			57
58		798	Unappropriated			58
59		798.5	Less treasury stock			59

60		799	Accumulated Other Comprehensive Income or (loss)			60
61			Total stockholders equity			61
62			Non-controlling interest			62
63			Total equity (Lines 61 + 62)			63
64			Total Liabilities & Shareholders' Equity			64

NOTES AND REMARKS

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Road Initials: **Year:** 7

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES
(Dollars in Thousands)

The notes listed below are provided to disclose supplementary information on matters which have an important effect on the financial condition of the carrier. The carrier shall give the particulars called for herein and where there is nothing to report, insert the word "none"; and in addition thereto shall enter in separate notes with suitable particulars other matters involving material amounts of the character commonly disclosed in financial statements under generally accepted accounting principles, except as shown in other schedules. This includes statements explaining (1) service interruption insurance policies and indicating the amount of indemnity to which respondent will be entitled for work stoppage losses and the maximum amount of additional premium respondent may be obligated to pay in the event such losses are sustained by other railroads; (2) particulars concerning obligations for stock purchase options granted to officers and employees; and (3) what entries have been made for net income or retained income restricted under provisions of mortgages and other arrangements.

1. Amount (estimated, if necessary) of net income or retained income which has to be provided for capital expenditures, and for sinking funds, pursuant to provisions of reorganization plans, mortgages, deeds of trust, or other contracts. ________________ $____________

2. Estimated amount of future earnings which can be realized before paying Federal income taxes because of unused and available net operating loss carryover on January 1 of the year following that for which the report is made. __________________ $____________

3. (a) Explain the procedure in accounting for pension funds and recording in the accounts the current and past service pension costs, indicating whether or not consistent with the prior year. ____

____

____

(b) State amount, if any, representing the excess of the actuarially computed value of vested benefits over the total of the pension fund.

____$______________________

(c) Is any part of the pension plan funded? Specify. Yes _____ No _____

If funding is by insurance, give name of insuring company ____

If funding is by trust agreement, list trustee(s) ____

Date of trust agreement or latest amendment ____

If respondent is affiliated in any way with the trustee(s), explain affiliation. ______________________________

____

(d) List affiliated companies which are included in the pension plan funding agreement and describe basis for allocating charges under the agreement.

____

(e) Is any part of the pension plan fund invested in stock or other securities of the respondent or its affiliates? Specify Yes ___ No ___

If yes, give number of the shares for each class of stock or other security. ______________________________

Are voting rights attached to any securities held by the pension plan? Specify Yes ___ No ___ If yes, who determines how stock is voted?

4. State whether a segregated political fund has been established as provided by the Federal Election Campaign Act of 1971 (18 U.S.C. 610).
Yes ___ No ___

5. (a) The amount of employer's contribution to employee stock ownership plans for the current year was $______________________

(b) The amount of investment tax credit used to reduce current income tax expense resulting from contributions to qualified employee stock ownership plans for the current year was $__________________

6. In reference to Docket 37465, specify the total amount of business entertainment expenditures charged to the non-operating expense account. $__________________

Continued on following page

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES – Continued

7. Give particulars with respect to contingent assets and liabilities at the close of the year, in accordance with instruction 5-6 in the Uniform System of Accounts for Railroad Companies, that are not reflected in the amounts of the respondent.

Disclose the nature and amount of contingency that is material.

Examples of contingent liabilities are items which may become obligations as a result of pending or threatened litigation, assessments or possible assessments of additional taxes, and agreements or obligations to repurchase securities or property. Additional pages may be added if more space is needed. (Explain and/or reference to the following pages.)

(a) Changes in valuation accounts.

8. Marketable equity securities.

		Cost	Market	Dr. (Cr.) to Income	Dr. (Cr.) to Stockholder's Equity
(Current Yr.)	Current Portfolio				N/A
as of / /	Noncurrent Portfolio			N/A	
(Previous Yr.)	Current Portfolio			N/A	N/A
as of / /	Noncurrent Portfolio			N/A	N/A

At / / , gross unrealized gains and losses pertaining to marketable equity securities were as follows:

	Gains	Losses
Current		
Noncurrent		

A net unrealized gain (loss) of $__________________ on the sale of marketable securities was included in net income for _____ (year)

The cost of securities was based on the _____________________ (method) cost of all the shares of each security held at time of sale.

Significant net realized and net unrealized gains and losses arising after date of the financial statements but prior to the filing, applicable to marketable equity securities owned at balance sheet date shall be disclosed below:

NOTE: / / (date) Balance sheet date of reported year unless specified as previous year.

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Road Initials: **Year:** **9**

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

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10 **Road Initials:** **Year:**

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

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Road Initials: **Year:** **11**

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

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200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

200. COMPARATIVE STATEMENT OF FINANCIAL POSITION - EXPLANATORY NOTES - Continued

NOTES TO FINANCIAL STATEMENTS

16	Road Initials:	Year:

210. RESULTS OF OPERATIONS

(Dollars in Thousands)

1. Disclose requested information for respondent pertaining to results of operations for the year.

2. Report total operating expenses from Sched. 410. Any differences between this schedule and Sched. 410 must be explained on page 1.

3. List dividends from investments accounted for under the cost method on line 19, and list dividends accounted for under the equity method on line 25.

4. All contra entries should be shown in parenthesis.

Cross-Checks

Schedule 210	Schedule 210
Line 15, col b	= Line 65, col b
Lines 47,48,49 col b	= Line 66, col b
Line 50, col b	= Line 67, col b
	Schedule 410
Line 14, col b	= Line 620, col h
Line 14, col d	= Line 620, col f
Line 14, col e	= Line 620, col g

Line No.	Cross Check	Item (a)	Amount for current year (b)	Amount for preceding year (c)	Freight-related revenue & Expense (d)	Passenger-related revenue & expenses (e)	Line No.
		ORDINARY ITEMS OPERATING INCOME Railway Operating Income					
1		(101) Freight					1
2		(102) Passenger					2
3		(103) Passenger-related					3
4		(104) Switching					4
5		(105) Water transfers					5
6		(106) Demurrage					6
7		(110) Incidental					7
8		(121) Joint facility – credit					8
9		(122) Joint facility – debit					9
10		(501) Railway operating revenues (Exclusive of transfers from government authorities-lines 1-9)					10
11		(502) Railway operating revenues - transfers from government authorities					11
12		(503) Railway operating revenues - amortization of deferred transfers from government authorities					12
13		TOTAL RAILWAY OPERATING REVENUES (lines 10-12)					13
14	*	(531) Railway operating expenses					14
15	*	Net revenue from railway operations					15
		OTHER INCOME					
16		(506) Revenue from property used in other than carrier operations					16
17		(510) Miscellaneous rent income					17
18		(512) Separately operated properties - profit					18
19		(513) Dividend income (cost method)					19
20		(514) Interest income					20
21		(516) Income from sinking and other funds					21

22		(517) Release of premiums on funded debt					22
23		(518) Reimbursements received under contracts and agreements					23
24		(519) Miscellaneous income					24
25		Income from affiliated companies: 519 a. Dividends (equity method)					25
26		b. Equity in undistributed earnings (losses)					26
27		TOTAL OTHER INCOME (lines 16-26)					27
28		TOTAL INCOME (lines 15, 27)					28
		MISCELLANEOUS DEDUCTIONS FROM INCOME					
29		(534) Expenses of property used in other than carrier operations					29
30		(544) Miscellaneous taxes					30
31		(545) Separately operated properties-Loss					31
32		(549) Maintenance of investment organization					32
33		(550) Income transferred under contracts and agreements					33
34		(551) Miscellaneous income charges					34
35		(553) Uncollectible accounts					35
36		TOTAL MISCELLANEOUS DEDUCTIONS					36
37		Income available for fixed charges					37

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Road Initials: **Year:** **17**

210. RESULTS OF OPERATIONS – Continued

(Dollars in Thousands)

Line No.	Cross Check	Item (a)	Amount for current year (b)	Amount for preceding year (c)	Line No.
38		FIXED CHARGES (546) Interest on funded debt: (a) Fixed interest not in default			38
39		(b) Interest in default			39
40		(547) Interest on unfunded debt			40
41		(548) Amortization of discount on funded debt			41
42		TOTAL FIXED CHARGES (lines 38 through 41)			42
43		Income after fixed charges (line 37 minus line 42)			43
44		OTHER DEDUCTIONS (546) Interest on funded debt: (c) Contingent interest			44
45		UNUSUAL OR INFREQUENT ITEMS (555) Unusual or infrequent items (debit) credit			45
46		Income (Loss) from continuing operations (before inc. taxes)			46
47	*	PROVISIONS FOR INCOME TAXES (556) Income taxes on ordinary income: (a) Federal income taxes			47
48	*	(b) State income taxes			48
49	*	(c) Other income taxes			49
50	*	(557) Provision for deferred taxes			50
51		TOTAL PROVISION FOR INCOME TAXES (lines 47 through 52)			51
52		Income from continuing operations (line 46 minus line 51)			52

		DISCONTINUED OPERATIONS				
53		(560) Income or loss from operations of discontinued segments (less applicable income taxes of $)				53
54		(562) Gain or loss on disposal of discontinued segments (less applicable income taxes of $)				54
55		Income before extraordinary items (lines 52 through 54)				55
		EXTRAORDINARY ITEMS AND ACCOUNTING CHANGES				
56		(570) Extraordinary items (Net)				56
57		(590) Income taxes on extraordinary items				57
58		(591) Provision for deferred taxes - Extraordinary items				58
59		TOTAL EXTRAORDINARY ITEMS (lines 56 through 58)				59
60		(592) Cumulative effect of changes in accounting principles (less applicable income taxes of $)				60
61	*	Net income (Loss) (lines 55 + 59 + 60)				61
62		Less: Net Income attributable to non-controlling interest				62
63		Net Income attributable to reporting railroad				63
64		Earnings Per Share, basic and diluted				64
		RECONCILIATION OF NET RAILWAY OPERATING INCOME (NROI)				
65	*	Net revenues from railway operations				65
66	*	(556) Income taxes on ordinary income (-)				66
67	*	(557) Provision for deferred income taxes (-)				67
68		Income from lease of road and equipment (-)				68
69		Rent for leased roads and equipment (+)				69
70		Net railway operating income (loss)				70

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18	**Road Initials:**	**Year:**

Notes and Remarks For Schedules 210 and 220

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19	**Road Initials:**	**Year:**

210 A. CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Dollars in Thousands)

1. This schedule applies only to entities with items of Other Comprehensive Income (OCI)

	Cross-Checks	
Schedule 210 Line 61, col b		Schedule 210 A = Line 1, col b

2. Entities must present comprehensive income in two separate but consecutive financial statements.

3. Entities must present reclassification adjustments and the effects of those adjustments on net income and OCI on the face of the financial statements.

4. All contra entries should be shown in parenthesis.

Line No.	Cross Check	Item (a)	Amount for current year (b)	Amount for preceding year (c)	Freight-related revenue & expenses (d)	Passenger-related revenue & expenses (e)	Line No.
1		Net Income					1
2		Other Comprehensive Income, net of tax Foreign currency translation adjustments					2
3		Unrealized gains on securities: Unrealized holding gains arising during period					3
4		Less: reclassification adjustment for gains included in net income					4
5		Defined benefit pension plans: Prior service cost arising during period					5
6		Net loss arising during period					6
7		Less: amortization of prior service cost included in net periodic pension cost					7
8		Other Comprehensive Income (lines 62+63-64-65-66+67)					8
		Comprehensive Income (Line 61 + 68)					
9		Less: comprehensive income attributable to non-controlling interest					9
10		Comprehensive Income attributable to reporting railroad (line 69-70)					10

Notes:

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[FR Doc. 2016–07759 Filed 4–5–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R9–IA–2011–0027; FF09A30000 123 FXIA16710900000R4]

RIN 1018–AW81

Endangered and Threatened Wildlife and Plants; U.S. Captive-Bred Inter-subspecific Crossed or Generic Tigers

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are amending the regulations that implement the Endangered Species Act (Act) by removing inter-subspecific crossed or generic tiger *(Panthera tigris)* (*i.e.*, specimens not identified or identifiable as members of Bengal, Sumatran, Siberian, or Indochinese subspecies *(Panthera tigris tigris, P. t. sumatrae, P. t. altaica,* and *P. t. corbetti,* respectively)) from the list of species that are exempt from registration under the Captive-bred Wildlife (CBW) regulations. The exemption currently allows those individuals or breeding operations who want to conduct otherwise prohibited activities, such as take, interstate commerce, and export under the Act with U.S. captive-bred, live inter-subspecific crossed or generic tigers, to do so without becoming registered. We make this change to the regulations to strengthen control over commercial movement and sale of tigers in the United States and to ensure that activities involving inter-subspecific crossed or generic tigers are consistent with the purposes of the Act. Inter-subspecific crossed or generic tigers are listed as endangered under the Act, and a person will need to obtain authorization under the current statutory and regulatory requirements to conduct any otherwise prohibited activities with them.

DATES: This rule becomes effective on May 6, 2016.

ADDRESSES: The supplementary materials for this rule, including the public comments received, are available at *http://www.regulations.gov* at Docket No. FWS–R9–IA–2011–0027. You may obtain information about permits or other authorizations to carry out otherwise prohibited activities by contacting the U.S. Fish and Wildlife Service, Division of Management Authority, Branch of Permits, 5275 Leesburg Pike, MS–IA, Falls Church, VA 22041–3803; telephone: 703–358–2104 or (toll free) 800–358–2104; facsimile: 703–358–2281; email: *managementauthority@fws.gov;* Web site: *http://www.fws.gov/international.*

FOR FURTHER INFORMATION CONTACT: Timothy J. Van Norman, Chief, Branch of Permits, Division of Management Authority, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS–IA, Falls Church, VA 22041–3803; telephone 703–358–2104; fax 703–358–2281. If you use a telecommunications devise for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

To prevent the extinction of wildlife and plants, the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (Act), and its implementing regulations in title 50 of the Code of Federal Regulations (CFR), prohibit any person subject to the jurisdiction of the United States from conducting certain activities with species listed under the Act unless first authorized by a permit, except as a rule issued under section 4(d) of the Act applies to the species. These activities include import, export, take, and sale or offer for sale in interstate or foreign commerce. The Secretary of the Interior may permit these activities for endangered species for scientific purposes or enhancement of the propagation or survival of the species, provided the activities are consistent with the purposes of the Act. In addition, for threatened species, permits may be issued for the above-listed activities, as well as zoological, horticultural, or botanical exhibition; education; and special purposes consistent with the Act. The Secretary of the Interior has delegated the authority to administer endangered and threatened species permit matters to the Director of the U.S. Fish and Wildlife Service. The Service's Division of Management Authority administers the permit program for the import or export of listed species, the sale or offer for sale in interstate and foreign commerce for nonnative listed species, and the take of nonnative listed wildlife within the United States.

Previous Federal Action

In 1979, the Service published the Captive-bred Wildlife (CBW) regulations (44 FR 54002, September 17, 1979) to reduce Federal permitting requirements and facilitate captive breeding of endangered and threatened species under certain conditions. These conditions include:

(1) A person may become registered with the Service to conduct otherwise prohibited activities when the activities can be shown to enhance the propagation or survival of the species;

(2) Interstate commerce is authorized only when both the buyer and seller are registered for the same species;

(3) The registration is only for live, mainly nonnative endangered or threatened wildlife that was born in captivity in the United States (although the Service may determine that a native species is eligible for the registration; to date, the only native species granted eligibility under the registration is the Laysan duck *(Anas laysanensis)*);

(4) Registration does not authorize activities with non-living wildlife, a provision that is intended to discourage the propagation of endangered or threatened wildlife for consumptive markets; and

(5) The registrants are required to maintain written records of authorized activities and report them annually to the Service. The CBW registration has provided zoological institutions and breeding operations the ability to move animals quickly between registered institutions for breeding purposes.

In 1993, the Service amended the CBW regulations at 50 CFR 17.21(g) (58 FR 68323, December 27, 1993) to eliminate public education through exhibition of living wildlife as the sole justification for the issuance of a CBW registration. That decision was based on the Service's belief that the scope of the CBW system should be revised to relate more closely to its original intent, *i.e.*, the encouragement of responsible breeding that is specifically designed to help conserve the species involved (63 FR 48635; September 11, 1998).

In 1998, the Service amended the CBW regulations (63 FR 48634, September 11, 1998) to delete the requirement to obtain a CBW registration for holders of inter-subspecific crossed or generic tigers (*i.e.*, specimens not identified or identifiable as members of Bengal, Sumatran, Siberian, or Indochinese subspecies *(Panthera tigris tigris, P. t. sumatrae, P. t. altaica,* and *P. t. corbetti,* respectively)). Certain otherwise prohibited activities with these specimens were authorized only when the activities were shown to enhance the propagation or survival of the species, provided the principal purpose was to facilitate captive breeding. Although the submission of a written annual report was not required, holders of these specimens had to maintain accurate written records of activities, including births, deaths, and transfers of specimens, and make the records accessible to Service agents for inspection at reasonable hours as provided for in 50 CFR 13.46 and 13.47. The exemption for inter-subspecific crossed or generic tigers was based on the lack of conservation value of these specimens due to their mixed or unknown genetic composition. The intention behind the exemption was for the Service to focus its oversight on populations of "purebred" animals of the various tiger subspecies to further their conservation in the wild, while recognizing that generic tigers that were currently held by zoological facilities could be used to educate the public about the ecological role and conservation needs of the species. Even with this exemption, inter-subspecific crossed or generic tigers were still protected under the Act and those activities that did not constitute authorized activities under the CBW program, such as the interstate sale of generic tigers solely for education purposes or display purposes, would require prior authorization of an ESA permit.

On August 22, 2011, the Service proposed to amend the CBW regulations that implement the Act by removing inter-subspecific crossed or generic tigers from paragraph (g)(6) of 50 CFR 17.21 (76 FR 52297). The public was provided with a 30-day comment period to submit their views and comments on the proposed rule. However, due to the large volume of comments, the Service published a notice on September 21, 2011 (76 FR 58455), extending the comment period for an additional 30 days. This comment period ended on October 21, 2011. Since that time, the Service has received no new substantive information that would affect this rule.

Species Status

The wild tiger was once abundant throughout Asia. At the end of the 19th century, an estimated 100,000 tigers occurred in the wild (Nowak 1999, p. 828), but by the late 1990s, the estimated population had declined to 5,000–7,000 animals (Seidensticker et al. 1999, p. xvii). Today's population in the wild is thought to be 3,000–5,000 individuals, according to the IUCN (International Union for Conservation of Nature) Red List estimate (Chundawat et al. 2010, unpaginated), with no more than 2,500 mature breeding adults (Williamson and Henry 2008, pp. 7, 43). The once-abundant tiger now lives in small, fragmented groups, mostly in protected forests, refuges, and national parks (FWS 2010a, p. 1). The species occupies only about 7 percent of its original range, and in the past decade, the species' range has decreased by as much as 41 percent (Dinerstein et al. 2007, p. 508).

For many years, the international community has expressed concern about the status of tigers in the wild and the risk that captive tigers, if used for consumptive purposes, may sustain the demand for tiger parts, which would ultimately have a detrimental effect on the survival of the species in the wild. An estimated 5,000 captive tigers occur on China's commercial tiger farms, where tigers are being bred intensively and produce more than 800 animals each year (Williamson and Henry 2008, p. 40). Tiger body parts, such as organs, bones, and pelts, are in demand not only in China, but also on the global black market. Organs and bones are used in traditional medicines, which are purchased by consumers who believe the parts convey strength, health, and virility.

Current regulations under the ESA prohibit the taking of any tiger, including generic tigers, and there is no clear evidence that the U.S. captive tiger population has played a role in illegal international trade. However, in 2005, Werner (p. 24) estimated that 4,692 tigers were held in captivity in the United States. Approximately 264 tigers were held in institutions registered with the Association of Zoos and Aquariums (AZA), 1,179 in wildlife sanctuaries, 2,120 in institutions registered by the U.S. Department of Agriculture (USDA), and 1,120 in private hands. In 2008, Williamson and Henry stated that as many as 5,000 tigers are in captivity in the United States, but cautioned that, given the current State and Federal legal framework that regulates U.S. captive tigers, the exact size of the population is unknown (Williamson and Henry 2008).

Conservation Status

The tiger is a species of global concern, is classified as endangered in the IUCN Red List (IUCN 2010), and is protected by a number of U.S. laws and treaties. It is listed as endangered under the Act. Section 3 of the Act defines an "endangered species" as "any species which is in danger of extinction throughout all or a significant portion of its range." The listing is at the species level and, thus, includes all subspecies of tiger (including those that are of unknown subspecies, referred to as "generic" tigers) and inter-subspecific crosses.

The species is also protected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Under this treaty, 178 member countries (Parties) work together to ensure that international trade in protected species is not detrimental to the survival of wild populations. The United States and all the tiger range countries are Parties to CITES. The tiger is listed in Appendix I, which includes species threatened with extinction whose trade is permitted only under exceptional circumstances, and which generally precludes commercial trade. The United States has a long history of working within CITES to promote tiger conservation and has been a leader in supporting strong actions within CITES for tigers, including strict controls on captive-bred animals. In 2007 at the 14th meeting of the Conference of the Parties to CITES (CoP14), we were closely involved in drafting Decision 14.69, which calls on countries with intensive commercial breeding operations of tigers to implement measures to restrict the captive population to a level supportive only to conserving wild tigers, and for tigers not to be bred for trade in their parts and products. Although the decision was primarily directed at large commercial breeding operations such as those found in China, we are aware of the large number of captive tigers in the United States and the need to be vigilant in monitoring these tigers as well.

The tiger is afforded additional protection under the Captive Wildlife Safety Act (CWSA) and the Rhinoceros and Tiger Conservation Act (RTCA, 16 U.S.C. 5301 *et seq.*). The CWSA amended the Lacey Act (16 U.S.C. 3371 *et seq.*) to address concerns about public safety and the growing number of big cats, including tigers, in private hands in the United States. The law and its regulations make it illegal to import, export, transport, sell, receive, acquire, or purchase in interstate or foreign commerce any live big cats except by certain exempt entities. Entities exempt from the CWSA include a person, facility, or other entity licensed by the USDA's Animal and Plant Health Inspection Service under the Animal Welfare Act to possess big cats (typically zoos, circuses, and researchers) or registered to transport big cats; State colleges, universities, and agencies; State-licensed wildlife rehabilitators and veterinarians; and wildlife sanctuaries that meet certain criteria.

The RTCA is another powerful tool in combating the international trade in products containing tiger parts. It prohibits the sale, import, and export of products intended for human use and containing, or labeled or advertised as containing, any substance derived from tiger and provides for substantial criminal and civil penalties for violators. The RTCA also establishes a fund that allows the Service to grant money in support of on-the-ground tiger conservation efforts, such as anti-poaching programs, habitat and ecosystem management, development of nature reserves, wildlife surveys and monitoring, management of human-wildlife conflict, and public awareness campaigns (FWS 2010b. p. 1).

Concerns Raised and Recommendations

The World Wildlife Fund, TRAFFIC North America, other nongovernmental organizations (NGOs), and the public have expressed concerns about the potential role U.S. captive tigers may play, or could potentially play, in the trade in tiger parts. In July 2008, TRAFFIC published a report titled, *Paper Tigers? The Role of the U.S. Captive Tiger Population in the Trade in Tiger Parts* (Williamson and Henry 2008). The report found no indication that U.S. tigers currently are entering domestic or international trade as live animals or as parts and products. However, given the precarious status of tigers in the wild and the potential that U.S. captive tigers could enter trade and undermine conservation efforts, TRAFFIC made several recommendations to close potential loopholes in current Federal and State regulations to avoid the use of captive U.S. tigers in trade. One of those recommendations was for the Service to eliminate the exemption under 50 CFR 17.21(g)(6) for holders of inter-subspecific crossed or generic tigers from the requirements to register and submit annual reports under the CBW regulations.

Summary of Comments and Our Responses

In our proposed rule (August 22, 2011; 76 FR 52297), we asked interested parties to submit comments or suggestions regarding the proposal to eliminate inter-subspecific crossed or generic tigers from the regulation at 50 CFR 17.21(g). The original comment period for the proposed rule lasted for 30 days, ending September 21, 2011. The comment period was extended, however, on September 21, 2011 (76 FR 58455), to allow for an additional 30 days to accommodate the large number of commenters. The extended comment period ended on October 21, 2011. We received 15,199 individual comments during the two comment periods. The vast majority of the comments (approximately 15,000) either supported the proposed rule as written or stated that it was not strong enough to address captive breeding of inter-subspecific crossed or generic tigers. We received 109 comments from individuals or organizations that opposed the proposed rule. The remaining 79 comments were either irrelevant to the proposed rule or indecipherable.

Issue 1: Approximately 14,300 comments supported the proposed rule as written, stated that this change in the regulations would reduce the level of illegal trade in both captive and wild tigers, decrease the possibility of captive tigers being held in inhumane conditions, and reduce "rampant" breeding of captive tigers within the United States. However, many of these commenters were also concerned that the change in the regulation would result in the possible overcrowding of sanctuaries or unaccredited institutions that would receive unwanted adult tigers.

Our response: The change in regulations would provide for greater control over captive tigers within the United States. As the CBW regulations are currently written, individuals or institutions that have been housing inter-subspecific crossed or generic tigers could move tigers across State lines for commercial activities without registering under the CBW regulations. While these activities are required to be undertaken in association with a managed breeding program to ensure that deleterious breeding (*i.e.*, inbreeding or inappropriate crosses) does not occur, we have evidence that these requirements may have been violated in some number of cases. Therefore, based on this conclusion, we are acting consistently with the purposes of the Act to limit the authorization of interstate commerce and commercial movement of tigers under the CBW regulations to situations where the end-use of the tiger is to enhance the propagation or survival of the species in the wild by contributing to the conservation of the species.

However, this change in regulations would not directly result in the control of breeding of inter-specific crossed or generic tigers. The Act does not regulate intrastate activities that do not result in a take or the noncommercial interstate movement of a listed species. The only intrastate activity that the Act regulates is the take (*e.g.*, harming, harassing, or killing) of a listed species. Individuals or facilities that maintain such tigers can continue to breed tigers, sell them within their State, or move tigers across State lines for noncommercial purposes without obtaining authorization from us, as long as such activities do not result in a take of the species. However, it is possible that stricter regulation of the interstate commerce of these specimens may result in a reduction in breeding due to a smaller (*i.e.*, intrastate only) market for generic tigers.

It is also possible that, with this change in the CBW regulations and the potentially lower demand for tigers within the United States, individuals or facilities that currently hold inter-subspecific crossed or generic tigers will move their animals to sanctuaries or other zoo facilities, causing these facilities to become overcrowded. We do not believe that such movement will become a significant problem at most zoos and sanctuaries, which generally maintain a high standard of care and, in any case, are required by the Animal Welfare Act and other Federal and State laws and regulations to provide humane treatment for animals. A need may arise, however, for greater coordination between nongovernmental organizations, zoos, and sanctuaries to ensure that all inter-subspecific crossed or generic tigers that end up in sanctuaries or zoos receive adequate housing and care.

Issue 2: Of the nearly 15,000 comments that supported the rule in some form, 527 commenters were opposed to maintaining tigers in captivity at all. These commenters expressed a general belief that tigers should be left in the wild and that captive tigers should be released. While many of these comments supported the change in regulations as necessary, they also expressed the belief that this change should be only the first step that would eventually result in captive tigers being released into the wild and/or no longer bred in captivity.

Our response: As stated above, the Act does not prohibit the ownership of listed species, if the activities being carried out with these specimens do not violate any of the prohibitions of the Act. Therefore, if the animals were legally purchased and moved, the Act does not prohibit an individual or institution from maintaining or even breeding tigers. While we recognize that some people are opposed to maintaining exotic animals in captivity, we do not have the regulatory authority to prohibit such activities. Further, we do not believe that inter-subspecific crossed or generic tigers are suitable for release in the wild, both because they may not be genetically compatible with wild populations, and because, in most cases, they are not suitably conditioned for survival in the wild. Such animals either might starve or could become a menace to livestock and humans. However, we believe that, under the correct circumstances, maintaining listed species in captivity—including tigers—can provide a conservation benefit to the species through education, research, and scientifically based breeding programs.

Issue 3: Many commenters (160) requested that we establish stricter regulations for tigers than what was proposed. Suggestions included establishing regulations that would prohibit anyone from holding or breeding tigers and allow only accredited zoos or sanctuaries to hold tigers. Many of these commenters expressed the desire to eliminate the use of tigers in circuses and animal exhibitions. The comments included suggestions to increase control over breeding programs and to have more frequent inspections of facilities to monitor for abuse or substandard facilities. Some commenters suggested microchipping all captive tigers. Some comments recommended stiffer penalties for poachers within the tiger native range.

Our response: As stated previously, the Act prohibits certain activities with listed species, but does not prohibit every activity that could involve such species. The Act does not regulate ownership or what an owner may do with a tiger as long as the owner obtained the tiger legally and does not harm or kill the tiger or engage in interstate commerce with the animal. We cannot establish regulations that go beyond the prohibitions of the Act, such as limiting ownership or breeding of tigers only to certain institutions or individuals. Anyone may engage in these activities if he or she otherwise complies with all other provisions of the Act, and as long as the actions are legal under other applicable laws (*e.g.,* those of the State in which the activities take place).

When we issue a permit or other authorization under the Act for otherwise prohibited activities, we do have the authority to conduct periodic inspections or otherwise have oversight of permitted activities. This authority, however, does not extend to activities outside the scope of the Act or for activities that are not regulated by the Act. Therefore, we do not have the ability to conduct regular inspections of breeding operations that do not require authorization from us. This type of inspection may be possible in some cases under the Animal Welfare Act, which is implemented by the USDA, but is outside the scope of this regulation. However, if we have evidence of illegal activity, we have the authority to carry out criminal investigations of any facility, whether or not it is permitted.

While we could require microchipping of tigers at a facility that has obtained a permit or other authorization from the Service, we cannot require the microchipping of all tigers within the United States. Microchipping some tigers may give us the ability to track the movement of live animals that are involved in interstate commerce (an otherwise prohibited activity), but we would not be able to track live tigers that do not fall under our jurisdiction. Further, microchipping is unlikely to assist us in investigating the illegal movement of tiger parts within the United States. We also do not have the authority or the resources to monitor and record the birth, death, or transfer of all tigers in the United States. Microchipping a portion of the captive tigers in the United States for tracking purposes might give us a limited picture of the movement and ownership of these animals in the United States, but we do not believe that any limited benefits would outweigh the cost and administrative burden of microchipping and tracking these animals.

We strongly encourage and support programs established by tiger range countries to control and ultimately eliminate poaching of wild tigers. We have been able to fund a variety of anti-poaching programs through various grant programs, including grants under the RTCA. We have also been actively involved in efforts through CITES to assist range countries in monitoring and controlling illegal trade in tigers. We do not have any authority, however, to establish stricter regulations regarding poaching in other countries.

Issue 4: One commenter was of the opinion that the exemption from the CBW registration process violated section 10(c) of the Act since it did not allow the public an opportunity to comment on the merits of activities involving inter-specific crossed or generic tigers.

Our response: By removing the exemption and requiring the submission of an application to either request a permit or register under the CBW regulations, the public will now have an opportunity to comment on the merits of any application to conduct otherwise prohibited activities with tigers.

Issue 5: Many commenters (109) were opposed to removing the exemption. In general, they believe that inter-subspecific crossed or generic tigers contribute to conservation primarily through education, but also by acting as a source of tigers within the United States. Many of these commenters felt that requiring registration under the CBW regulations or requiring a permit to conduct otherwise prohibited activities would ultimately lead to the demise of captive tigers in the United States. Many of these commenters expressed their concern that wild tigers will go extinct in the near future due to habitat loss and poaching, and, therefore, captive-bred tigers are needed to ensure that the species does not go extinct.

Our response: The CBW regulations facilitate the captive breeding of species listed under the Act for conservation purposes by allowing registrants to conduct interstate commerce and move specimens across State lines. The Service recognizes that well-managed breeding programs focusing on specific subspecies and that maintain good genetic diversity among the specimens within the breeding program can provide a long-term benefit to listed species by producing a pool of viable candidates for future reintroduction. We have also stated in the 1998 final rule exempting inter-subspecific crossed or generic tigers from the CBW registration process (63 FR 48638) that inter-subspecific crossed or generic tigers should not be used for conservation-oriented breeding, but could be used for exhibition in a manner designed to educate the public about the ecological role and conservation needs of the species.

The Act does not regulate intrastate activities other than take, such as ownership and breeding, nor does it regulate noncommercial interstate transfers of listed species (*e.g.,* gifts, loans, and exchanges of animals of the same species for genetic management purposes). Removing the exemption for inter-subspecific crossed or generic tigers from the CBW regulations will require anyone who is selling an inter-subspecific crossed or generic tiger across State lines to either register under the CBW regulations or obtain an interstate commerce permit. The Service does not believe that the action taken in this final rule will adversely affect the conservation breeding of tigers within the United States, nor lead to the demise of captive tigers within the United States.

Issue 6: Several commenters expressed the opinion that enough laws or restrictions are already in place to ensure that the legality of activities carried out with tigers. Two commenters pointed directly to the RTCA as a powerful tool to combat illegal trade of tiger parts within the United States. These commenters stated that, since there is no proof of the use of U.S. captive tigers in traditional medicines, the Service does not need to impose additional regulations on tiger breeders in the United States. Five commenters felt that, because there is no proof of such illegal trade within the United States, such trade is not a threat, and, therefore, this rule is arbitrary and capricious under the Administrative Procedure Act.

Our response: While we agree with the commenters on the benefits of the RTCA in combating illegal trade in tiger parts, we do not agree that the existing regulations adequately provide for the conservation of tigers. With the exemption for inter-subspecific crossed or generic tigers, it was difficult to determine whether activities involving tigers were legal because there was no requirement for a permit or other authorization. Monitoring of activities was also hampered by our inability to determine if tigers bred and sold under the exemption were actually inter-subspecific crossed or generic animals. By removing the exemption, we are reinstating regulations that already cover most other endangered and threatened species, thus ensuring better oversight and monitoring. This requirement will be another tool that can be used, in conjunction with the RTCA and other laws, to curb potentially illegal activities within the United States. While we have no evidence indicating that captive tigers are currently being illegally killed for their parts within the United States, we believe that, if wild tiger populations continue to decline, demand for captive tigers and their parts may increase. The final rule is reasonable in light of this potential threat and evidence of continuing declines in tiger population and range, and we have fully explained our reasons for removing the exemption.

Issue 7: Two commenters felt that we made contradictory statements in the proposed rule when we said that individuals who wished to carry out otherwise prohibited activities with inter-subspecific crossed or generic tigers would need to register under the CBW regulations, but then also stated that we did not believe the breeding of inter-subspecific crossed or generic tigers provided a conservation benefit. In other words, they concluded that we would not actually register anyone with inter-subspecific crossed or generic tigers because of our perceived lack of conservation value of such animals.

Our response: The commenters are correct that we do not believe that breeding inter-subspecific crossed or generic tigers, in and of itself, provides a conservation benefit, since the tigers are of unknown or mixed genetic origin. As such, inter-subspecific crossed or generic tigers would not be good candidates for a well-managed conservation-oriented breeding program. In addition, it is unlikely that we would register an operation for the sole purpose of selling tigers across State lines, since a CBW registration is for the purpose of exchanging stock with other breeders or to hold surplus animals not needed for a breeding program. This does not mean, however, that we could not authorize individual permits if the activity being conducted enhanced the propagation or survival of the species in the wild. Under our regulations, it is possible to authorize interstate commerce for an inter-subspecific crossed or generic tiger if the parties involved in the transaction are carrying out activities that enhance the propagation or survival of the species. While it is unlikely that such a commercial transaction would provide a direct benefit to the species, such as reintroduction, there may be indirect benefits that could be obtained from the transaction.

It should also be noted that the requirement to show that authorizing an otherwise prohibited activity, such as interstate commerce, could be met through an individual or institution, or a group of individuals or institutions together, working to provide a benefit to the species in the wild. For example, if one or more zoological institutions were purchasing inter-subspecific crossed or generic tigers for educational and display purposes, they could provide support (*e.g.,* via the solicitation of donations from visitors) to carry out in-situ conservation efforts in the tiger's native range. The Service prefers a clear, ongoing commitment of several years on the part of the applicant to provide in-situ conservation or research support. This ongoing commitment could be fulfilled by a group of institutions working together to maximize their resources for the benefit of tigers in the wild.

Issue 8: Several commenters stated that inter-subspecific crossed or generic tigers have an educational value and, therefore, should still be exempt from the CBW registration to ensure that this benefit could continue. Many of these commenters felt that inter-subspecific crossed or generic tigers are "ambassadors" for the wild tiger and its conservation. One commenter stated that availability of such tigers within the United States removed pressure on wild populations to supply animals for exhibition purposes. One commenter, noting that the Service previously excluded education as a sole justification for registration under the CBW regulations, questioned the basis of this exclusion.

Our response: This rule does not address whether the display of inter-subspecific crossed or generic tigers has an educational value. It is possible that a professionally developed education program using inter-subspecific crossed or generic tigers could indirectly benefit the wild populations of tigers by raising public awareness of the plight of the tiger. Furthermore, no permit or other authorization, including a CBW registration, is necessary to conduct educational programs with such tigers, including crossing State lines to make presentations involving the animals. Given the number of inter-subspecific crossed or generic tigers within the United States, the commenter is correct that wild-caught tigers are not in demand for educational purposes. The purpose of this rule, however, is to reestablish the monitoring and oversight benefits of the CBW regulations to all specimens of tigers, not just purebred specimens.

On December 27, 1993, the Service published a final rule (58 FR 68323) that eliminated public education through exhibition of living wildlife as the sole justification for issuing a CBW registration under § 17.21(g). As one commenter correctly pointed out, the Service made the statement in the 1998 final rule exempting inter-subspecific crossed or generic tigers from the CBW registration process (63 FR 48638) that inter-subspecific crossed or generic tigers should not be used to enhance the propagation of the species, but could be used for exhibition in a manner designed to educate the public about the ecological role and conservation needs of the species. While individuals are not precluded from continuing to provide educational opportunities to the public through the display of inter-subspecific crossed or generic tigers, an educational purpose alone is not enough to support CBW registration per the 1993 rule. The basis for excluding education as the sole justification for a CBW registration was discussed in the final rule on that issue (58 FR 68323) and is outside the scope of this rulemaking.

Issue 9: Two commenters raised questions about the listing status of the inter-subspecific crossed or generic tiger. One commenter questioned whether inter-subspecific crossed or generic tigers meet the standard of listing under the Act and, therefore, whether they are properly subject to regulation by the Service. Another commenter proposed that inter-subspecific crossed or generic tigers within the United States are a new subspecies, the "American tiger." This commenter provided a description of six "varieties" of "American tigers" that should be, as a group, a new subspecies.

Our response: Whether these animals meet the listing criteria under section 4 of the Act is an issue outside the scope of this rulemaking process. Whether inter-subspecific crossed or generic tigers within the United States would constitute a separate subspecies is a matter that should be addressed by taxonomists and is, therefore, outside the scope of this rulemaking process as well. However, currently the tiger is listed at the species level, not at the subspecies level, so all tiger specimens are covered by the listing.

Issue 10: One commenter noted a study by the National Cancer Institute that found that one "generic" tiger in seven is actually a purebred member of a recognized subspecies, raising the question of how individuals can determine if their tiger is pure or an inter-subspecific crossed or generic tiger. Another commenter raised the question of whether this rule would require genetic testing of tigers and how the cost of that testing would be covered.

Our response: The first commenter was probably referring to a study published in 2008 in *Current Biology*[1] that found 14–23 percent (approximately 1 in 7 or more) of the "generic" tigers tested were shown to have a verifiable subspecies ancestry (*i.e.,* they are a pure subspecies). The tigers tested in this study came from locations in the United States and abroad. We note that our definition of "generic tiger" includes animals of unknown lineage. It is entirely possible that some animals of unknown lineage actually have a pure subspecies lineage, but the lack of information on their origin requires that they be treated as unknown for the purposes of conservation breeding.

Since pure and generic tigers would be treated the same in regards to permits issued under 50 CFR 17.22 (*i.e.,* interstate and foreign commerce, take, import, or export), there would be no requirement to test tigers within the United States. However, if the owner of a breeding operation wished to become a CBW registrant, that person would need to show how the tigers he or she holds would contribute to the genetic management of the species within the United States. If the owner is unable to document the source and, therefore, subspecies of their tigers, it may be necessary to conduct genetic testing on his/her tigers to prove that they are not inter-specific crossed animals. The cost of such testing would be his/her responsibility.

Issue 11: One commenter questioned the value of maintaining pure subspecies in captivity as a potential pool for reintroduction purposes if the plight of the wild tiger is so dire. The commenter's presumption was that zoos and private breeders do not have the capacity to maintain sufficient numbers of pure subspecies to provide enough specimens if reintroduction is needed. It is unclear whether the commenter meant that a need might develop to use tigers of mixed or unknown genetic ancestry for reintroduction purposes and that the survival of the species may rely on such tigers. However, the commenter expressed the view that efforts by the Service to limit the breeding of inter-subspecific crossed or generic tigers are counterintuitive to the conservation of the species.

Our response: The generally accepted approach to the captive breeding of tigers—or of any species—for conservation purposes is to maintain separate viable populations of each subspecies and to avoid, where possible, breeding tigers of unknown or questionable genetic heritage. Adequacy of founder representation and minimum viable population sizes are issues to be determined by conservation biologists and vary depending on the biological characteristics of the species, and are outside the scope of this rulemaking. The purpose of this rule is to establish a single approach to monitoring the otherwise prohibited activities involving any tiger within the United States.

Issue 12: One commenter felt that the display of inter-subspecific crossed or generic tigers could generate funds for in-situ conservation efforts and should, therefore, be encouraged.

Our response: We agree that the display of tigers, whether purebred subspecies or tigers of unknown genetic ancestry, could generate funds and resources for in-situ conservation efforts. This rule does not limit nor is it intended to discourage in-situ conservation efforts. The rule only provides the same level of monitoring and oversight for all tigers within the United States to ensure that activities carried out with this species are legal and consistent with the purposes of the Act.

Removal of Inter-subspecific Crossed or Generic Tigers from 50 CFR 17.21(g)(6)

We are amending the CBW regulations that implement the Act by removing inter-subspecific crossed or generic tiger *(Panthera tigris)* (*i.e.,* specimens not identified or identifiable as members of Bengal, Sumatran, Siberian, or Indochinese subspecies *(Panthera tigris tigris, P. t. sumatrae, P. t. altaica,* and *P. t. corbetti,* respectively)) from paragraph (g)(6) of 50 CFR 17.21. This action eliminates the exemption from registering and reporting under the CBW regulations by persons who want to conduct otherwise prohibited activities under the Act with live, inter-subspecific crossed or generic tigers born in the United States. This action does not alter the current listing of tigers. Inter-subspecific crossed or generic tigers remain listed as endangered under the Act, and a person would need to qualify for an exemption or obtain an authorization under the remaining statutory and regulatory requirements to conduct any prohibited activities.

We are changing the regulations to ensure that we maintain stricter control over the commercial movement and sale of captive tigers in the United States. As stated in the comment section, we do not believe that breeding inter-subspecific crossed or generic tigers, in and of itself, provides a conservation benefit for the long-term survival of the species. Inter-subspecific tiger crosses and animals of unknown genetic ancestry could not be used for maintaining genetic viability and distinctness of specific tiger subspecies. Tigers of unknown or mixed genetic origin are typically not maintained in a manner to ensure that inbreeding or other inappropriate matings of animals do not occur. By exempting inter-subspecific crossed or generic tigers from the CBW registration process in 1998, we had inadvertently suggested that the breeding of these tigers, in and of itself, qualifies as conservation. By removing the exemption, we reinforce the value of conservation breeding of individual tiger subspecies through the CBW program.

As stated in the proposed rule, we are unaware of any evidence that tiger parts are entering into trade from the captive U.S. population of tigers. However, we recognize that the use of tiger parts and products, including in traditional medicine, poses a significant threat to wild tiger populations. The United States has worked vigorously with other CITES countries to encourage not only the adoption of measures to protect wild tiger populations from poaching and illegal trade, but also the implementation of measures to ensure that breeding of tigers in captivity supports conservation goals and that tigers are not bred for trade in parts and products. While we do not have evidence that parts from captive-bred tigers in the United States are currently entering into international trade, we believe that demand for tiger parts could increase in the future. This threat, combined with the precarious status of tigers in the wild, lead us to conclude that the oversight provided by this final rule will benefit the species.

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[1] Shu-Jin Luo, Warren E. Johnson, Janice Martenson, Agostinho Antunes, Paolo Martelli, Olga Uphyrkina, Kathy Traylor-Holzer, James L.D. Smith and Stephen J. O'Brien. 2008. "Subspecies Genetic Assignments of Worldwide Captive Tigers Increase Conservation Value of Captive Populations". *Current Biology*, 18, 592–596.

The previous CBW exemption also created enforcement difficulties. Specifically, law enforcement cases have hinged on whether activities the Service has identified as illegal were actually exempted under the current regulations. By removing the exemption, persons engaged in otherwise prohibited activities will need to obtain a permit or register under the CBW program, giving the Service greater ability to bring enforcement cases for violations involving tigers.

It should be stressed, however, that removing the exemption for inter-subspecific crossed or generic tigers would not result in regulations by the Service of ownership, intrastate commerce, or noncommercial movement of these tigers across State lines, as long as they are not killed or harmed. These activities are not prohibited by the Act, and we have no authority to prohibit or otherwise regulate them.

Finally, we reorganized paragraph (g)(6), redesignating subparagraphs to make the section clearer. With the exception of removing inter-subspecific crossed or generic tigers, the text is essentially the same as it previously appeared in 50 CFR 17.21(g)(6).

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563): Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is significant because it may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act: Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions) (5 U.S.C. 601 *et seq.*). However, no regulatory flexibility analysis is required if the head of an agency certifies that the rule would not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for "significant impact" and a threshold for a "substantial number of small entities." See 5 U.S.C. 605(b). SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule would not have a significant economic impact on a substantial number of small entities.

The U.S. Small Business Administration (SBA) defines a small business as one with annual revenue or employment that meets or is below an established size standard. We expect that the majority of the entities involved in taking, exporting, re-importing, and selling in interstate or foreign commerce of inter-subspecific crossed or generic tigers would be considered small as defined by the SBA.

Currently, businesses conducting activities with inter-subspecific crossed or generic tigers are exempt from registration under the CBW regulations, if the activities are consistent with the purposes of the ESA and CBW program. This rule would require businesses that are otherwise carrying out these activities to apply for authorization under the Act and pay an application fee of $100 for a one-time interstate commerce permit or $200 to register under the CBW program (valid for 5 years).

Currently, there is no Federal or State mechanism in place that tracks or monitors the extent of business activities involving generic tigers. With the exemption from registration by facilities that are conducting activities in compliance with the current CBW regulations, FWS does not have data on how many businesses are involved in the interstate commerce of generic tigers, the number of businesses for which an interstate commerce permit or registration in the CBW program will be a viable option, and the economic impacts if prospective applicants are unable to either secure an interstate commerce permit or registration in the CBW program. While the U.S. Department of Agriculture regulates some aspects of holding large cats like tigers, their authority does not extend to all facilities that maintain tigers. As such, there is not a centralized database or collection of data that would identify the number of facilities within the United States. While some State governments may monitor or even regulate some aspects of holding tigers, either pure-bred or generic, there is not a universal approach that would render any significant data on those facilities that hold tigers throughout the United States. Nonetheless, based on the comments received during the public comment period, FWS anticipates that the number of affected small businesses is small and either registration in the CBW program or an interstate commerce permit will be a viable option at a modest expense. Therefore, the regulatory change is not major in scope and will create only a modest financial or paperwork burden on the affected members of the public.

We, therefore, certify that this rule would not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required.

Small Business Regulatory Enforcement Fairness Act: This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Would not have an annual effect on the economy of $100 million or more. This rule removes the inter-subspecific crossed or generic tigers from the exemption to register under the CBW regulations. Individuals and captive-breeding operations would need to obtain endangered species permits or other authorization to engage in certain otherwise prohibited activities. This rule would not have a negative effect on the economy. It will affect all businesses, whether large or small, the same. There is not a disproportionate share of benefits for small or large businesses.

b. Would not cause a major increase in costs or prices for consumers;

individual industries; Federal, State, tribal, or local government agencies; or geographic regions. This rule would result in a small increase in the number of applications for permits or other authorizations to conduct otherwise prohibited activities with inter-subspecific crossed or generic tigers.

c. Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act: Under the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

a. This rule would not significantly or uniquely affect small governments. A Small Government Agency Plan is not required.

b. This rule would not produce a Federal requirement of $100 million or greater in any year and is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

Takings: Under Executive Order 12630, this rule would not have significant takings implications. A takings implication assessment is not required. This rule is not considered to have takings implications because it allows individuals to obtain authorization for otherwise prohibited activities with the inter-subspecific crossed or generic tigers when issuance criteria are met.

Federalism: This revision to part 17 does not contain significant Federalism implications. A Federalism Assessment under Executive Order 13132 is not required.

Civil Justice Reform: Under Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of subsections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act: This rule does not contain any new information collections or recordkeeping requirements for which Office of Management and Budget (OMB) approval is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). OMB has reviewed and approved the information collection requirements for the Division of Management Authority's permit program and assigned OMB Control Number 1018–0093, which expires May 31, 2017. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (NEPA): The Service has determined that this action is a regulatory change that is administrative and procedural in nature. This rule requires that persons engaging in otherwise prohibited activities with inter-subspecific crossed or generic tigers register under the CBW regulations at 50 CFR 17.21(g), but does not change the standards in regard to prohibited activities or exemptions from these prohibitions in any way. Previously, any otherwise prohibited activity with an inter-subspecific crossed or generic tiger had to be for the purpose of enhancing the propagation or survival of the species, and that standard has not changed. Other requirements such as limitations with respect to nonliving wildlife, identification of animals to be re-imported, requirements for animals to be permanently exported, and recordkeeping requirements have not changed. The difference is that persons conducting these activities with inter-subspecific crossed or generic tigers that previously did not have to register will now have to register with the Service. As such, the amendment is categorically excluded from further NEPA review as provided by 43 CFR 46.210(i), of the Department of the Interior Implementation of the National Environmental Policy Act of 1969 final rule (73 FR 61292; October 15, 2008). No further documentation will be made.

Government-to-Government Relationship with Tribes: Under the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we have evaluated possible effects on federally recognized Indian Tribes and have determined that there are no effects.

Energy Supply, Distribution or Use: Executive Order 13211 pertains to regulations that significantly affect energy supply, distribution, and use. This rule would not significantly affect energy supplies, distribution, and use. Therefore, this action is a not a significant energy action and no Statement of Energy Effects is required.

Data Quality Act: In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554).

References Cited

A complete list of references cited in this rulemaking is available on the Internet at *http://www.regulations.gov* at Docket No. FWS–R9–IA–2011–0027 and upon request from the person listed in **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting, and recordkeeping requirements, Transportation.

Regulation Promulgation

For the reasons given in the preamble, we are amending part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.21 by revising paragraph (g)(6) to read as set forth below:

§ 17.21 Prohibitions.

* * * * *

(g) * * *

(6) *Exemption from registration requirement.* (i) If the conditions in paragraph (g)(6)(ii) of this section are met, then any person subject to the jurisdiction of the United States seeking to engage in any of the activities authorized by paragraph (g)(1) of this section may do so without first registering with the Service with respect to the following species:

(A) The bar-tailed pheasant *(Syrmaticus humiae),* Elliot's pheasant *(S. ellioti),* Mikado pheasant *(S. mikado),* brown eared pheasant *(Crossoptilon mantchuricum),* white eared pheasant *(C. crossoptilon),* cheer pheasant *(Catreus wallichii),* Edward's pheasant *(Lophura edwardsi),* Swinhoe's pheasant *(L. swinhoii),* Chinese monal *(Lophophorus lhuysii),* and Palawan peacock pheasant *(Polyplectron emphanum);*

(B) Parakeets of the species *Neophema pulchella* and *N. splendida;*

(C) The Laysan duck *(Anas laysanensis);* and

(D) The white-winged wood duck *(Cairina scutulata).*

(ii) *Conditions for exemption to register.* The following conditions must exist for persons dealing with the species listed in paragraph (g)(6)(i) of this section to be eligible for exemption from the requirement to register with the Service:

(A) The purpose of the activity is to enhance the propagation or survival of the affected exempted species.

(B) Such activity does not involve interstate or foreign commerce, in the course of a commercial activity, with respect to nonliving wildlife.

(C) Each specimen to be reimported is uniquely identified by a band, tattoo, or other means that was reported in writing to an official of the Service at a port of export prior to export of the specimen from the United States.

(D) No specimens of the taxa in paragraph (g)(6)(i) of this section that were taken from the wild may be imported for breeding purposes absent a definitive showing that the need for new bloodlines can be met only by wild specimens, that suitable foreign-bred, captive individuals are unavailable, and that wild populations can sustain limited taking. In addition, an import permit must be issued under § 17.22.

(E) Any permanent exports of such specimens meet the requirements of paragraph (g)(4) of this section.

(F) Each person claiming the benefit of the exception in paragraph (g)(1) of this section must maintain accurate written records of activities, including births, deaths, and transfers of specimens, and make those records accessible to Service agents for inspection at reasonable hours as set forth in §§ 13.46 and 13.47 of this chapter.

* * * * *

Dated: March 24, 2016.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–07762 Filed 4–5–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–6211–02]

RIN 0648–XE557

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the B season apportionment of the 2016 Pacific cod total allowable catch allocated to trawl catcher vessels in the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), April 4, 2016, through 1200 hours, A.l.t., June 10, 2016.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The B season apportionment of the 2016 Pacific cod total allowable catch (TAC) allocated to trawl catcher vessels in the BSAI is 5,460 metric tons (mt) as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the B season apportionment of the 2016 Pacific cod TAC allocated to trawl catcher vessels in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 5,000 mt and is setting aside the remaining 460 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by catcher vessels using trawl gear in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific cod by catcher vessels using trawl gear in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 31, 2016.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 1, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–07905 Filed 4–1–16; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 66
Wednesday, April 6, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2016–0026]

Privacy Act of 1974; Implementation of Exemptions; Department of Homeland Security/U.S. Customs and Border Protection–014 Regulatory Audit Archive System (RAAS) System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security is giving concurrent notice of an updated and reissued system of records pursuant to the Privacy Act of 1974 for the "Department of Homeland Security/U.S. Customs and Border Protection–014 Regulatory Audit Archive System of Records" and this proposed rulemaking. This system of records will continue to manage audits that are part of DHS/CBP's continuing oversight of customs brokers, importers, and other parties engaged in international trade activities, that are the subject of a regulatory audit or are identified in and related to the scope of an audit report.

In this proposed rulemaking, the Department proposes to reduce the number of exemptions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments must be received on or before May 6, 2016.

ADDRESSES: You may submit comments, identified by docket number DHS–2016–0026 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: John Connors, (202) 344–1610, Privacy Officer, U.S. Customs and Border Protection, Privacy and Diversity Office, 1300 Pennsylvania Avenue NW., Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP) is giving notice of a proposed rule to accompany an updated system of records notice titled, "DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records."

DHS/CBP conducts regulatory audits in support of its oversight of customs brokers licensed by DHS/CBP pursuant to 19 U.S.C. 1641 to act as agents for importers in the entry of merchandise and payment of duties and fees. This system of records covers records about importers and other parties engaged in international trade activities that are the subject of a regulatory audit or are identified in and related to the scope of an audit report.

Concurrent with this NPRM, elsewhere in the **Federal Register**, DHS/CBP is updating the "DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records" categories of records, authorities, and routine uses. DHS/CBP is updating the categories of records to include the collection of Employer Identification Numbers (EINs) or Social Security numbers (SSNs), also known as Federal Taxpayer Identifying Number, pursuant to 19 CFR 24.5, 19 CFR 149.3, and E.O. 9397, *as amended* by E.O. 13748. DHS/CBP collects this additional data to align RAAS with information provided by importers through the DHS/CBP Automated Commercial Environment System (ACE) data-source. DHS/CBP is also clarifying the category of records to include business and audit records collected or created as part of the audit process.

DHS/CBP is clarifying the authorities section to include updated and more narrowly tailored authorities to permit the collection of EIN or SSN. 19 CFR 24.5 and 19 CFR 149.3 require that DHS/CBP collect Federal Taxpayer Identifying Numbers in association with services resulting in issuance of a bill or refund check upon adjustment of a cash collection or to document entities that are liable for payment of all duties and responsible for meeting all statutory or regulatory requirements incurred as a result of importation. Individuals or entities that do not have a SSN may submit an EIN in lieu of the SSN for merchandise entry purposes.

DHS/CBP is making non-substantive edits to the Routine Uses A–G to align with previously published Departmental SORNs. This notice also includes non-substantive changes to simplify the formatting and texts of the previously published notice.

Consistent with DHS's information sharing mission, information stored in DHS/CBP–014 RAAS may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/CBP may share information with appropriate Federal, State, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

DHS/CBP previously published a Final Rule in the **Federal Register** to exempt this system of records from certain provisions of the Privacy Act at 74 FR 45076 (August 31, 2009). DHS/CBP proposes to reduce the number of exemptions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements. The existing Final Rule for Privacy Act exemptions continues to apply until the new Final Rule is published. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

The Privacy Act allows government agencies to exempt certain records from the access and amendment provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is claimed.

DHS is revising the previously claimed exemptions from certain requirements of the Privacy Act for DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records. DHS/CBP is not requesting an exemption with respect to information maintained in the system as it relates to data submitted by or on behalf of a subject of an audit. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agency has sought particular records may affect ongoing law enforcement activity. Therefore, pursuant to 5 U.S.C. 552a(k)(2), DHS will claim exemption from sec. (c)(3) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information.

Some information in DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records relates to official DHS law enforcement activities. These exemptions are needed to protect information relating to DHS law enforcement activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required to preclude subjects of these activities from frustrating these processes; to avoid disclosure of activity techniques; to protect the identities and physical safety of confidential informants and law enforcement personnel; to ensure DHS's ability to obtain information from third parties and other sources; to protect the privacy of third parties; and to safeguard classified information. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

The exemption proposed here is a standard law enforcement exemption exercised by a large number of Federal law enforcement agencies. In appropriate circumstances, when compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case-by-case basis.

A system of records notice for DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records is also published in this issue of the **Federal Register**.

List of Subjects in 6 CFR Part 5

Freedom of information, Privacy.

For the reasons stated in the preamble, DHS proposes to amend chapter I of title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: Pub. L. 107–296, 116 Stat. 2135; (6 U.S.C. 101 *et seq.*); 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

■ 2. In appendix C to part 5, revise paragraph 25 to read as follows:

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

25. The Department of Homeland Security/U.S. Customs and Border Protection-014 Regulatory Audit Archive System (RAAS) System of Records consists of electronic and paper records and will be used by DHS and its Components. The DHS/CBP–014 RAAS System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to: The enforcement of civil and criminal laws; investigations, inquiries, and proceedings there under. The DHS/CBP–014 RAAS System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its Components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security, pursuant to 5 U.S.C. 552a(k)(2), has exempted this system from the following provisions of the Privacy Act: 5 U.S.C. 552a(c)(3). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsec. (c)(3) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to

(b) tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

* * * * *

Dated: March 22, 2016.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–07894 Filed 4–5–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 251, 271, 272, and 277

[FNS–2016–0028]

RIN 0584–AE44

Supplemental Nutrition Assistance Program Promotion; Correction

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Proposed rule; correction.

SUMMARY: This document contains a correction to the proposed rule published in the **Federal Register** on March 14, 2016, "Supplemental Nutrition Assistance Program Promotion." The Food and Nutrition Service published a proposed rule in the **Federal Register**, 81 FR 13290, on March 14, 2016, to implement section 4018 of the Agricultural Act of 2014. Section 4018 created new limitations on the use of federal funds authorized in the Food and Nutrition Act of 2008 (FNA), for the Supplemental Nutrition Assistance Program (SNAP) promotion and outreach activities. The summary of the proposed rule is being corrected to aid in clarity to the reader.

DATES: To be assured of consideration, written comments must be received on or before May 13, 2016.

FOR FURTHER INFORMATION CONTACT: Mary Rose Conroy, Branch Chief, Program Development Division, Program Design Branch, Food and Nutrition Services, U.S. Department of Agriculture, 3101 Park Center Drive, Room 810, Alexandria, VA 22302, or by phone at (703) 305–2803, or by email at *Maryrose.conroy@fns.usda.gov.*

Correction

In proposed rule FR Doc. 2016–05583, beginning on page 13290 in the issue of March 14, 2016, make the following correction in the Summary section. On page 13290 the Summary section is revised to read as follows:

SUMMARY: This proposed rule would implement Section 4018 of the Agricultural Act of 2014. Section 4018 created new limitations on the use of federal funds authorized in the Food and Nutrition Act of 2008 (FNA), for the Supplemental Nutrition Assistance Program (SNAP) promotion and outreach activities. Specifically, Section 4018 of the 2014 Farm Bill prohibits the use of Federal funds appropriated in the FNA from being used for recruitment activities designed to persuade an individual to apply for SNAP benefits; television, radio, or billboard advertisements that are designed to promote SNAP benefits and enrollment; or agreements with foreign governments designed to promote SNAP benefits and enrollment. The prohibition on using funds appropriated under the FNA for television, radio, or billboard advertisements does not apply to Disaster SNAP.

Section 4018 also prohibits any entity that receives funds under the FNA from compensating any person engaged in outreach or recruitment activities based on the number of individuals who apply to receive SNAP benefits. Lastly, Section 4018 modifies Section 16(a)(4) of the FNA to prohibit the Federal government from paying administrative costs associated with recruitment activities designed to persuade an individual to apply for program benefits or that promote the program through television, radio, or billboard advertisements.

This proposed rule would also impact the Food Distribution Program on Indian Reservations (FDPIR) and The Emergency Food Assistance Program (TEFAP), both of which receive funding and/or foods authorized under the FNA.

Dated: March 22, 2016.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2016–07454 Filed 4–5–16; 8:45 am]

BILLING CODE 3410–30–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 123

RIN 3245–AG78

Disaster Assistance Loan Program; Disaster Loan Mitigation, Contractor Malfeasance and Secured Threshold

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to amend its disaster loan program regulations in response to changes made to the Small Business Act (the Act) by the Recovery Improvements for Small Entities After Disaster Act of 2015 (the RISE Act). The first change would expand the definition of a mitigating measure to include the construction of a safe room or similar storm shelter designed to protect property and occupants. The second change would allow for an increase of the unsecured threshold for physical damage loans for non-major disasters. The third change would allow SBA to increase loan amounts to address contractor malfeasance. In addition, SBA proposes to make several technical corrections to conform certain regulatory provisions to existing statutory authority and remove an obsolete reference in part 123.

DATES: Comments must be received on or before June 6, 2016.

ADDRESSES: You may submit comments, identified by RIN 3245–AG78, by any of the following methods: (1) Federal Rulemaking Portal: *http://regulations.gov.* Follow the specific instructions for submitting comments; (2) Fax: (202) 205–7728 or Email *James.Rivera@sba.gov;* or (3) Mail/Hand Delivery/Courier: James E. Rivera, Associate Administrator for Disaster Assistance, 409 3rd Street SW., Washington, DC 20416.

SBA will post all comments to this proposed rule on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* you must submit such information to U.S. Small Business Administration, Jerome Edwards, Office of Disaster Assistance, 409 3rd Street SW., Mail code 2990, Washington, DC 20416, or send an email to *Jerome.Edwards@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review your information and determine whether it will make the information public.

FOR FURTHER INFORMATION CONTACT: Jerome Edwards, Office of Disaster Assistance 202–205–6734 or *Jerome.Edwards@sba.gov.*

SUPPLEMENTARY INFORMATION: Section 7(b) of the Small Business Act, 15 U.S.C. 636(b), authorizes SBA to make direct loans to homeowners, renters, businesses, and non-profit organizations that have been adversely affected by a disaster. After a declared disaster, SBA makes loans of up to $200,000 to homeowners and renters (plus up to $40,000 for personal property) and loans of up to $2 million to businesses of all sizes and non-profit organizations to assist with any uninsured and otherwise uncompensated physical losses sustained during the disaster. In addition to loans for the repair or replacement of damaged physical property, SBA also offers working capital loans, known as Economic Injury Disaster Loans (EIDLs), to small businesses, small agricultural cooperatives, and most private non-profit organizations that have suffered economic injury caused by a disaster. The maximum loan amount is $2 million for physical and economic injuries combined. SBA may waive this $2 million limit if a business is a major source of employment.

The Recovery Improvements for Small Entities After Disaster Act of 2015, Public Law 114–88, 129 Stat. 686 (November 25, 2015), amended certain terms and conditions of SBA's Disaster Assistance program. As discussed below, this rulemaking proposes to implement three of those amendments, as set out in sections 1102, 2102 and 2107 of the RISE Act. SBA also proposes to make several minor technical amendments to the program regulations that, among other things, would ensure consistency between the program's regulatory and statutory authorities.

Changes Made as a Result of the RISE Act

Section 1102 of the RISE Act, Use of Physical Damage Disaster Loans to Construct Safe Rooms, expanded the definition of mitigation to include "construction of a safe room or similar storm shelter designed to protect property and occupants from tornadoes or other natural disasters, if such safe room or similar storm shelter is constructed in accordance with applicable standards issued by the Federal Emergency Management Agency." This change allows SBA to include a safe room or storm shelter as a mitigating measure; therefore, SBA proposes to amend 13 CFR 123.21 to reflect this change in the definition of a mitigation measure. By policy, SBA increases the amount of a disaster loan for mitigation purposes only when the mitigation protects or mitigates against damage from the same type of occurrence as the declared disaster. Revised § 123.21 would also clarify that a mitigation measure is something done for the purpose of protecting property (real and personal) and occupants. In addition, safe rooms and storm shelters would be included in the examples of mitigation measures.

Section 2102 of the RISE Act, Collateral Requirements for Disaster Loans, increased SBA's unsecured loan limits for all disaster loans for a period of three years. In 2014, SBA published an Interim Final Rule, Disaster Assistance Loan Program; Disaster Loan Credit and Collateral Requirements (79 FR 22859, April 25, 2014), to raise the unsecured limit to $25,000 for economic injury loans for all disasters and for physical damage loans for major disasters. The unsecured limit for physical damage loans for non-major disasters continued to be $14,000, in accordance with the Small Business Act. Section 2102 of the RISE Act expanded on these previous changes by increasing the unsecured limit to $25,000 to include physical damage loans for non-major disasters for a period of three years, until November 25, 2018. Therefore, SBA proposes to amend 13 CFR 123.11 to reflect a $25,000 unsecured threshold for all disaster declarations. After November 25, 2018, the unsecured limit for physical damage loans for non-major disasters would revert back to $14,000, unless Congress makes the increase permanent.

Section 2107 of the RISE Act, Contractor Malfeasance, expanded SBA's ability to provide disaster assistance by expressly allowing for supplemental assistance for malfeasance by a contractor or other person and defining what constitutes malfeasance. Prior to implementation of the RISE Act, SBA provided assistance only for malfeasance by contractors, not malfeasance by any "other person" in connection with the loan, and did not allow for increases in the loan amount beyond the regulatory limit of $200,000 for repair or replacement of damaged property. The RISE Act gave SBA authority to increase a disaster loan when a contractor or other person engages in malfeasance in connection with repairs to, rehabilitation of, or replacement of property for which SBA made a disaster loan and the malfeasance results in substantial economic damage or substantial risks to health or safety. SBA proposes to revise 13 CFR 123.18, 123.20, and 123.105 to include details on what constitutes malfeasance, provide guidance on when borrowers are eligible to apply for loan increases due to malfeasance, and allow home loan borrowers to increase their loans up to an additional $200,000 for malfeasance. For business loans, the total maximum loan amount, including any increase for malfeasance, remains $2,000,000.

The proposed changes made as a result of the RISE Act apply to all eligible recipients of SBA disaster loans for disasters declared on or after the effective date of the RISE Act, November 25, 2015.

Technical Corrections

In addition to the changes proposed as a result of the RISE Act, SBA is also proposing to make several technical corrections. SBA proposes to change the phrase "sudden physical event" to "sudden event" in 13 CFR 123.2 to conform the regulation to SBA's statutory definition of "disaster" in 15 U.S.C. 632(k). SBA proposes to revise 13 CFR 123.3 to remove the reference to "emergency" declarations in § 123.3(a)(1) in order to conform the regulations to SBA's statutory authority. SBA proposes this change to clarify that SBA disaster assistance is not automatically authorized when the President declares an emergency; such assistance may be available, however, if SBA declares a disaster under its own authority. Finally, SBA proposes to revise 13 CFR 123.13(a) to remove the reference to an expired OMB control number.

SBA invites comments from interested members of the public on all changes proposed in this rule. These comments must be received on or before the close of the comment period noted in the DATES section of this document.

Compliance with Executive Orders 12866, 12988, 13132, and 13563 and the Paperwork Reduction Act (44 U.S.C. Ch. 35) and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this proposed rule does not constitute a significant regulatory action under Executive Order 12866. This is not a major rule under the Congressional Review Act, 5 U.S.C. 800.

Executive Order 12988

This action meets applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden. This action does not have preemptive or retroactive effect.

Executive Order 13132

For the purposes of Executive Order 13132, this proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, SBA determined that this proposed rule has no federalism implications warranting preparation of a federalism assessment.

Executive Order 13563

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements and are affording the public 60 days to participate and provide comments.

Paperwork Reduction Act (44 U.S.C. Ch. 35)

For purpose of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this proposed rule would not impose any new reporting or recordkeeping requirements.

Regulatory Flexibility Act (5 U.S.C. 601–612)

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601, requires administrative agencies to consider the effect of their actions on small entities, including small businesses. According to the RFA, when an agency issues a rule, the agency must prepare an analysis to determine whether the impact of the rule will have a significant economic impact on a substantial number of small entities. However, the RFA allows an agency to certify a rule in lieu of preparing an analysis if the rulemaking is not expected to have a significant impact on a substantial number of small entities. This proposed rule conforms to recent legislative action made under the RISE Act and will implement new agency policies regarding the expansion of the definition of mitigation as it pertains to the Disaster Loan Program, and the inclusion of malfeasance.

List of Subjects in 13 CFR Part 123

Disaster assistance, Loan programs-business, Reporting and recordkeeping requirements, Small businesses.

For reasons set forth in the preamble, SBA proposes to amend 13 CFR part 123 as follows:

PART 123—DISASTER LOAN PROGRAM

■ 1. The authority citation for part 123 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(b), 636(d), 657n; Pub. L. 102–395, 106 Stat. 1828, 1864; Pub. L. 103–75, 107 Stat. 739; and Pub. L. 106–50, 113 Stat. 245.

■ 2. Amend § 123.2 by revising the seventh sentence to read as follows:

§ 123.2 What are disaster loans and disaster declarations?

* * * Sudden events that cause substantial economic injury may be disasters even if they do not cause physical damage to a victim's property. * * *

■ 3. Amend § 123.3 by revising paragraph (a)(1) to read as follows:

§ 123.3 How are disaster declarations made?

(a) * * *

(1) The President declares a Major Disaster and authorizes Federal Assistance, including individual assistance (Assistance to Individuals and Households Program).

* * * * *

4. Amend § 123.11 by revising paragraph (a)(2) to read as follows:

§ 123.11 Does SBA require collateral for any of its disaster loans?

(a) * * *

(2) *Physical disaster home and physical disaster business loans.* Generally, SBA will not require that you pledge collateral to secure a physical disaster home or physical disaster business loan of $25,000 or less. This authority expires on November 25, 2018, unless extended by statute.

* * * * *

§ 123.13 [Amended]

■ 5. Amend § 123.13 by removing the parenthetical phrase "(OMB Approval No. 3245–0122.)" from paragraph (a).

■ 6. Amend § 123.18 by:

■ a. Redesignating the undesignated text as paragraph (a);

■ b. Revising the first sentence of the redesignated paragraph (a); and

■ c. Adding paragraph (b).

The revisions and additions read as follows:

§ 123.18 Can I request an increase in the amount of a physical disaster loan?

(a) Generally, SBA will consider your request for an increase in your loan if you can show that the eligible cost of repair or replacement of damages increased because of events occurring after the loan approval that were beyond your control.* * *

(b) For all disasters occurring on or after November 25, 2015, you may also request an increase in your loan if you suffered substantial economic damage or substantial risks to health or safety as a result of malfeasance in connection with the repair or replacement of real property or business machinery and equipment for which SBA made a disaster loan. See § 123.105 for limits on home loan amounts and § 123.202 for limits on business loan amounts. Malfeasance may include, but is not limited to, nonperformance of all or any portion of the work for which a contractor was paid, work that does not meet acceptable standards, or use of substandard materials.

■ 7. Amend § 123.20 by redesignating the undesignated text as paragraph (a) and adding paragraph (b) to read as follows:

§ 123.20 How long do I have to request an increase in the amount of a physical disaster loan or an economic injury loan?

(a) * * *

(b) For physical disaster loan increases requested under § 123.18(b) as a result of malfeasance, the request must be received not later than two years after the date of final disbursement.

■ 8. Amend § 123.21 by revising the first and third sentences to read as follows:

§ 123.21 What is a mitigation measure?

A mitigation measure is something done for the purpose of protecting property and occupants against disaster related damage.* * * Examples of mitigation measures include building retaining walls, sea walls, grading and contouring land, elevating flood prone structures, relocating utilities, constructing a safe room or similar storm shelter (if such safe room or similar storm shelter is constructed in accordance with applicable standards issued by the Federal Emergency Management Agency), or retrofitting structures to protect against high winds, earthquakes, flood, wildfires, or other physical disasters.* * *

■ 9. Amend § 123.105 by:

■ a. Revising paragraph (a) introductory text;

■ b. Removing the word "and" from paragraph (a)(3);

■ c. Revising paragraph (a)(4); and

■ d. Adding paragraph (a)(5).

The revisions and additions read as follows:

§ 123.105 How much can I borrow with a home disaster loan and what limits apply on use of funds and repayment terms?

(a) There are limits on how much money you can borrow for particular purposes:

* * * * *

(4) 20 percent of the verified loss (not including refinancing or malfeasance), before deduction of compensation from other sources, up to a maximum of $200,000 for post-disaster mitigation (see § 123.107); and

(5) $200,000 for eligible malfeasance, pursuant to § 123.18.

* * * * *

Dated: March 30, 2016.

Maria Contreras-Sweet,

Administrator.

[FR Doc. 2016–07750 Filed 4–5–16; 8:45 am]

BILLING CODE 8025–01–P

FEDERAL TRADE COMMISSION

16 CFR Part 460

RIN 3084–AB40

Labeling and Advertising of Home Insulation

AGENCY: Federal Trade Commission ("FTC" or "Commission").

ACTION: Advance notice of proposed rulemaking; request for public comment.

SUMMARY: As part of the Commission's systematic review of all current FTC rules and guides, the Commission requests public comment on the overall costs, benefits, necessity, and regulatory and economic impact of the FTC's "Trade Regulation Rule Concerning the Labeling and Advertising of Home Insulation" (the "R-value Rule" or "Rule").

DATES: Comments must be received on or before June 6, 2016.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "16 CFR part 460—R-value Rule Review, File No. R811001" on your comment, and file your comment online at *https://*

ftcpublic.commentworks.com/ftc/rvaluerule by following the instructions on the web-based form. If you prefer to file your comment on paper, write "16 CFR part 460—R-value Rule Review, Matter No. R811001" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Hampton Newsome, (202) 326–2889, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

Thermal insulation is an important energy-savings product that reduces consumers' heating and cooling costs and increases their home energy efficiency. The Commission promulgated the R-value Rule, found at 16 CFR part 460 ("the current Rule" or "the current R-value Rule"), in 1979 to address the failure of the home insulation marketplace to provide essential pre-purchase information to consumers, primarily an insulation product's "R-value."[1] An insulation product's "R-value" rates the product's ability to restrict heat flow and, therefore, reduce energy costs. The higher the R-value, the better the product's insulating ability. R-value ratings vary among different types and forms of home insulations and even among products of the same type and form.

The FTC's current R-value Rule provides substantiation and disclosure requirements for insulation products used in the residential market and prohibits certain claims unless they are true. Specifically, the current Rule requires insulation sellers to disclose the insulation product's R-value and related information for their products based on uniform, industry-adopted test procedures.[2] This information enables consumers to evaluate the performance and cost effectiveness of competing insulation products.

A. Products Covered

The R-value Rule covers all "home insulation products." Under the current Rule, the term "insulation" includes any product "mainly used to slow down heat flow" from, for example, a heated interior through exterior walls to the outside.[3] The current Rule covers most types or forms of insulation marketed for use in residential structures, whether or not the Rule specifically refers to such insulation.[4] It does not cover insulation sold for use in commercial (including industrial) buildings. In addition, it generally does not apply to non-insulation products with insulating characteristics, such as storm windows or storm doors.

Home insulation falls into two basic categories: "mass" and "reflective." Mass insulations reduce heat transfer by conduction (through the insulation's mass), convection (air movement within, and through, the air spaces inside the insulation), and radiation. Reflective insulations (primarily aluminum foils) reduce heat transfer when installed facing an airspace. Within these basic categories, home insulation is sold in various types or materials (*e.g.*, fiberglass, cellulose, polyurethane, aluminum foil) and forms (*e.g.*, batt, dry-applied loose-fill, spray-applied, board stock, multi-sheet reflective).

B. Covered Parties

The current Rule applies to home insulation manufacturers, professional installers, retailers who sell insulation to consumers for do-it-yourself installation, and new home sellers, including sellers of manufactured housing. It also applies to testing laboratories that conduct R-value tests for home insulation manufacturers or other sellers who base their R-value claims on these test results.

C. The Rule's Basis

The Commission first issued the current R-value Rule in response to a variety of unfair or deceptive acts or practices in the insulation industry. Specifically, the Commission found that many sellers: (1) Failed to disclose R-values, impeding informed purchasing decisions and misleading consumers who based their purchases on price or thickness alone; (2) exaggerated R-value disclosures and often failed to account for material factors (*e.g.*, aging, settling) that reduce thermal performance; (3) failed to inform consumers about R-value's meaning and importance; (4) exaggerated fuel bill savings and often did not disclose that savings vary depending on consumers' particular circumstances; or (5) falsely claimed that consumers' insulation purchases would qualify for tax credits, or that products had been "certified" or "favored" by Federal agencies.[5]

D. The Rule's Requirements

The current Rule requires manufacturers and others who sell home insulation to disclose R-value and related information (*e.g.*, thickness, coverage area per package) on package labels and manufacturers' fact sheets. R-value disclosures must be derived from tests conducted according to one of four specified American Society of Testing and Materials ("ASTM") test procedures that measure thermal performance under "steady-state" (*i.e.*, static) conditions.[6] For mass insulations, the required tests include ASTM C–177, C–236, C–518, and C–976.[7] Industry members must conduct tests for mass insulation products on the insulation material alone (excluding any airspace) at a mean temperature of 75 °F. The current Rule requires testing for reflective insulation products according to either ASTM C 236–89 (1993) or ASTM C 976–90, which generate R-values for insulation systems (such as those that include one or more air spaces).[8] The current Rule's R-value

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[1] The Commission promulgated the current R-value Rule pursuant to section 18 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 57a. The current Rule became effective on September 30, 1980. *See* 44 FR 50218 (Aug. 27, 1979).

[2] Additional Commission rules or guides may also apply to home insulation sellers. For example, the Commission's rules concerning Disclosure of Written Consumer Product Warranty Terms and Conditions, and the Pre-sale Availability of Written Warranty Terms, 16 CFR parts 701 and 702, specify warranty requirements; and the Commission's Guides for the Use of Environmental Marketing Claims, 16 CFR part 260, address the application of section 5 of the FTC Act, 15 U.S.C. 45, to environmental advertising and marketing claims (*e.g.*, recycled material claims). Further, section 5 declares that unfair or deceptive acts or practices are unlawful, and requires that advertisers and other sellers have a reasonable basis for advertising and other promotional claims before they are disseminated. *See Deception Policy Statement,* appended to *Cliffdale Assoc., Inc.,* 103 FTC 110, 174 (1984); and *FTC Policy Statement on Unfairness,* appended to *International Harvester Co.,* 104 F.T.C. 949 (1984); and *Policy Statement Regarding Advertising Substantiation,* 49 FR 30999 (Aug. 2, 1984), *reprinted in Thompson Medical Co.,* 104 F.T.C. 839 (1984).

[3] *See* 16 CFR 460.2.

[4] 16 CFR part 460 does not cover pipe insulation or any type of duct insulation except for duct wrap.

[5] 44 FR at 50222–24 (Aug. 27, 1979).

[6] The current Rule incorporates by reference ASTM's test procedures, which ASTM reviews and revises periodically. Under § 460.7 of the Rule, the Commission will accept, but not require, the use of a revised version of any of these standards 90 days after ASTM adopts and publishes the revision. The Commission may, however, reopen the rulemaking proceeding during the 90-day period, or at any later time, to consider whether it should require use of the revised procedure or reject it under § 460.5.

[7] 44 FR 50218, at 50226, n. 189.

[8] The R-value of a single-sheet reflective insulation product must be tested under ASTM

Continued

tests account for certain factors that can affect insulation's thermal performance. For example, the current Rule's R-value tests for polyurethane, polyisocyanurate, and extruded polystyrene insulation account for aging, and the required tests for loose-fill insulation products reflect the effect of settling on R-values.[9]

The current Rule also requires specific disclosures on manufacturer product labels and fact sheets, installer receipts, and new home seller contracts. For example, insulation labels must display, among other things, the product's R-value and the statement "R means resistance to heat flow. The higher the R-value, the greater the insulating power." [10] The current Rule also requires that certain affirmative disclosures appear in advertising and other promotional materials (including those on the Internet) that contain an R-value, price, thickness, or energy-saving claim, or compare one type of insulation to another. For example, if an advertisement contains an R-value, it must disclose the type of insulation being sold and the thickness needed to get that R-value, as well as the statement: "The higher the R-value, the greater the insulating power. Ask your seller for the fact sheet on R-values." In addition, if an advertisement contains an energy saving claim, it must disclose: "Savings vary. Find out why in the seller's fact sheet on R-values. Higher R-values mean greater insulating power." [11]

II. Regulatory Review Program

The Commission reviews its rules and guides periodically to seek information about their costs and benefits, regulatory and economic impact, and general effectiveness in protecting consumers and helping industry avoid deceptive claims. These reviews assist the Commission in identifying rules and guides that warrant modification or rescission. As part of its last review in 2005, the Commission issued several amendments to update and improve the Rule.[12]

With this document, the Commission initiates a new review. The Commission solicits comments on, among other things, the economic impact of, and the continuing need for, the R-value Rule; the Rule's benefits to consumers; and the burdens it places on industry members subject to the requirements, including small businesses.

III. Issues for Comments

To aid commenters in submitting information, the Commission has prepared the following specific questions related to the R-value Rule. The Commission seeks comments on these and any other issues related to the Rule's current requirements. In their replies, commenters should provide any available evidence that supports their position.

A. General Regulatory Review Questions

(1) *Need:* Is there a continuing need for the Rule? Why or why not?

(2) *Benefits and Costs to Consumers:* What benefits has the Rule provided to consumers, and does the Rule impose any significant costs on consumers?

(3) *Benefits and Costs to Industry Members:* What benefits, if any, has the Rule provided to businesses, and does the Rule impose any significant costs, including costs of compliance, on businesses, including small businesses?

(4) *Recommended Changes:* What modifications, if any, should the Commission make to the Rule to increase its benefits or reduce its costs? How would these modifications affect the costs and benefits of the Rule for consumers? How would these modifications affect the costs and benefits of the Rule for businesses, particularly small businesses?

(5) *Impact on Information:* What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

(6) *Compliance:* Provide any evidence concerning the degree of industry compliance with the Rule. Does this evidence indicate that the Rule should be modified? If so, why, and how? If not, why not?

(7) *Unnecessary Provisions:* Provide any evidence concerning whether any of the Rule's provisions are no longer necessary. Explain why these provisions are unnecessary.

(8) *Additional Unfair or Deceptive Practices:* What potentially unfair or deceptive practices, not covered by the Rule, related to insulation products are occurring in the marketplace? Are such practices prevalent in the market? If so, please describe such practices, including their impact on consumers. Provide any evidence, such as empirical data, consumer perception studies, or consumer complaints, that demonstrates the extent of such practices. Provide any evidence that demonstrates whether such practices cause consumer injury. With reference to such practices, should the Rule be modified? If so, why, and how? If not, why not?

(9) *Product Coverage:* Should the Commission broaden the Rule to include products not currently covered? Provide any evidence that supports your position. What potentially unfair or deceptive practices related to products not covered by the Rule are occurring in the marketplace? Are such practices prevalent in the market? If so, please describe such practices, including their impact on consumers. Provide any evidence, such as empirical data, consumer perception studies, or consumer complaints, that demonstrates the extent of such practices. Provide any evidence that demonstrates whether such practices cause consumer injury.

(10) *Technological or Economic Changes:* What modifications, if any, should be made to the Rule to account for current or impending changes in technology or economic conditions? How would these modifications affect the costs and benefits of the Rule for consumers and businesses, particularly small businesses?

(11) *Conflicts With Other Requirements:* Does the Rule overlap or conflict with other Federal, State, or local laws or regulations? If so, how? Provide any evidence that supports your position. With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not? Are there any Rule changes necessary to help state law enforcement agencies combat deceptive practices in the insulation market? Provide any evidence concerning whether the Rule has assisted in promoting national consistency with respect to the advertising of insulation products.

B. Specific Questions Related to the R-Value Rule

(1) *Aging of Cellular Plastics:* Should the Commission update the required test procedures for the aging of cellular plastic insulations under 460.5(a)(1) to ensure consistency among R-value claims and to otherwise prevent deception? Specifically, should the Commission amend the Rule to require ASTM 1303 ("Standard Test Method for Predicting Long-Term Thermal Resistance of Closed-Cell Foam

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E408 or another test method that provides comparable results.

[9] 44 FR at 50219–20, 50227–28 (Aug. 27, 1979).

[10] 16 CFR 460.12(c).

[11] The current Rule requires manufacturers and other sellers to have a "reasonable basis" for any energy-saving claims they make. 16 CFR 460.19. Although the current Rule does not specify how they must substantiate such claims, the Commission explained when issuing the Rule that scientifically reliable measurements of fuel use in actual houses, or reliable computer models or methods of heat flow calculations, would meet the reasonable basis standard. 44 FR at 50233–34 (Aug. 27, 1979). Sellers other than manufacturers can rely on the manufacturer's claims unless they know, or should know, that the manufacturer lacks a reasonable basis for the claims.

[12] 70 FR 31258 (May 31, 2005).

Insulation") or a different test? If so, to which products should this test apply?[13]

(2) *Affirmative Disclosures:* Should the Commission consider changing, adding, or removing affirmative disclosures required by the Rule for labeling and advertising related to mass insulation, reflective insulation, or radiant barriers?

(3) *Foam Insulation:* Given the significant increase in the use of foam insulation products since the last Rule review, should the Commission consider any Rule changes to help prevent deception in the marketing of such products, or reduce unnecessary burdens on sellers?

(4) *Testing Requirements:* Should the Commission consider any changes to the testing provisions in the Rule? Such potential changes include, but are not limited to, test updates, the addition of new or existing tests not currently referenced in the Rule, or changes to other testing-related requirement such as the Rule's "tolerance" provision (§ 460.8).[14] Are there any tests currently referenced in the Rule that should be removed?

IV. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 6, 2016. Write "16 CFR part 460—R-value Rule Review, File No. R811001" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/r-valuereview,* by following the instruction on the web-based form. If this Notice appears at *http://www.regulations.gov,* you also may file a comment through that Web site.

If you prefer to file your comment on paper, write "16 CFR part 460—R-value Rule Review, File No. R811001" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex B), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this ANPR and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 6, 2016. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–07679 Filed 4–5–16; 8:45 am]

BILLING CODE 6750–01–P

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[13] Certain types of cellular plastics insulations (*e.g.,* polyurethane, polyisocyanurate, and extruded polystyrene boardstock insulations) contain a gas other than normal air in the product's voids (*i.e.,* small spaces or bubbles throughout the material). Such gas gives the product an initial R-value that is higher than it would have if the voids contained normal air. However, the R-value for these insulations decreases over time as the gas escapes the material and is replaced by normal air.

The current Rule addresses this aging process by requiring that R-value tests be performed on specimens that "fully reflect the effect of aging on the product's R-value." Section 460.5(a)(1) of the Rule accepts the use of the "accelerated aging" procedure in General Services Administration ("GSA") Purchase Specification HH–I–530A (which was in effect at the time the Commission promulgated the Rule) as a permissible "safe harbor" procedure, but also allows manufacturers to use "another reliable procedure."

[14] The tolerance provision (§ 460.8) states that no individual specimen of the insulation an industry member sells can have an R-value more than 10% below the R-value shown on the product's label.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0011]

RIN 1625–AA08

Special Local Regulation; Bucksport/Southeastern Drag Boat Summer Championships, Atlantic Intracoastal Waterway; Bucksport, SC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during the Bucksport/Southeastern Drag Boat Summer Championships, on August 13, and August 14, 2016. This special local regulation is necessary to ensure the safety of participants, spectators, and the general public during the event. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Charleston or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 6, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0011 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public

Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background, Purpose, and Legal Basis

On December 27, 2015, the Bucksport Marina notified the Coast Guard that it will sponsor a series of drag boat races from 12 p.m. to 7 p.m. on August 13, and August 14, 2016. The legal basis for the proposed rule is the Coast Guard's Authority to establish special local regulations: 33 U.S.C 1233. The purpose of the proposed rule is to ensure safety of life on the navigable water of the United States during the Bucksport/Lake Murray Drag Boat Spring Nationals, a series of high speed boat races.

III. Discussion of Proposed Rule

The Coast Guard proposes to establish a special local regulation on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during Bucksport/Southeastern Drag Boat Summer Championships, on August 13 and August 14, 2016. Approximately 75 powerboats are anticipated to participate in the races and approximately 35 spectator vessels are expected to attend the event. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders and we discuss the First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866, Regulatory Planning and Review, as supplemented by E.O. 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866 or under section 1 of E.O. 13563. The Office of Management and Budget has not reviewed it under those Orders.

The economic impact of this proposed rule is not significant for the following reasons: (1) The special local regulation would be enforced for only seven hours a day over a two day period; (2) although persons and vessels would not be able to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port Charleston or a designated representative, they would be able to operate in the surrounding area during the enforcement periods; (3) persons and vessels would still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the Captain of the Port Charleston or a designated representative; and (4) the Coast Guard would provide advance notification of the regulated area to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. We have considered the impact of this proposed rule on small entities. This rule may affect the following entities, some of which may be small entities: the owner or operators of vessels intending to enter, transit through, anchor in, or remain within the regulated area during the enforcement period. For the reasons discussed in Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves special local regulation issued in conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.T07–0011 to read as follows:

§ 100.T07–0011 Special Local Regulations; Bucksport/Southeastern Drag Boat Summer Championships, Atlantic Intracoastal Waterway, Bucksport, SC.

(a) *Regulated area.* All waters of the Atlantic Intracoastal Waterway encompassed by a line connecting the following points: point 1 in position 33°39′13″ N., 079°05′36″ W.; thence west to point 2 in position 33°39′17″ N., 079°05′46″ W.; thence south to point 3 in position 33°38′53″ N., 079°05′39″ W.; thence east to point 4 in position 33°38′54″ N, 079°05′31″ W.; thence north back to point 1. All coordinates are North American Datum 1983.

(b) *Definition.* As used in this section, "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area, except persons and vessels participating in Bucksport/Southeastern Drag Boat Summer Championships or serving as safety vessels. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843)740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(2) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement date.* This rule will be enforced daily on August 13 and August 14, 2016 from 12 p.m. until 7 p.m.

Dated: March 29, 2016.

G.L. Tomasulo,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2016–07898 Filed 4–5–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2016–0010]

RIN 1625–AA08

Special Local Regulation; Bucksport/Southeastern Drag Boat Summer Extravaganza, Atlantic Intracoastal Waterway; Bucksport, SC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a special local regulation on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during the Bucksport/Southeastern Drag Boat Summer Extravaganza, on July 9 and July 10, 2016. This special local regulation is necessary to ensure the safety of participants, spectators, and the general public during the event. This proposed rulemaking would prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Charleston or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 6, 2016.

ADDRESSES: You may submit comments identified by docket number USCG–2016–0010 using the Federal eRulemaking Portal at *http://www.regulations.gov.* See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant John Downing, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740–3184, email *John.Z.Downing@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
E.O.	Executive order
FR	Federal Register
NPRM	Notice of proposed rulemaking
Pub. L.	Public Law
§	Section
U.S.C.	United States Code

II. Background, Purpose, and Legal Basis

On December 27, 2015, the Bucksport Marina notified the Coast Guard that it will sponsor a series of drag boat races from 12 p.m. to 7 p.m. on July 9, and July 10, 2016. The legal basis for the proposed rule is the Coast Guard's Authority to establish special local regulations: 33 U.S.C 1233. The purpose of the proposed rule is to ensure safety of life on the navigable water of the United States during the Bucksport/Lake Murray Drag Boat Spring Nationals, a series of high speed boat races.

III. Discussion of Proposed Rule

The Coast Guard proposes to establish a special local regulation on the Atlantic Intracoastal Waterway in Bucksport, South Carolina during the Bucksport/Southeastern Drag Boat Summer Extravaganza, on July 9 and July 10, 2016. Approximately 75 powerboats are anticipated to participate in the races and approximately 35 spectator vessels are expected to attend the event. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative. The Coast Guard will provide notice of the special local regulation by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders and we discuss the First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This NPRM has not been designated a "significant regulatory action," under E.O. 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget.

This proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866, Regulatory Planning and Review, as supplemented by E.O. 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866 or under section 1 of E.O. 13563. The Office of Management and Budget has not reviewed it under those Orders.

The economic impact of this proposed rule is not significant for the following reasons: (1) The special local regulation would be enforced for only seven hours a day over a two-day period; (2) although persons and vessels would not be able to enter, transit through, anchor in, or remain within the regulated area without authorization from the Captain of the Port Charleston or a designated representative, they would be able to operate in the surrounding area during the enforcement periods; (3) persons and vessels would still be able to enter, transit through, anchor in, or remain within the regulated area if authorized by the Captain of the Port Charleston or a designated representative; and (4) the Coast Guard would provide advance notification of the regulated area to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. We have considered the impact of this proposed rule on small entities. This rule may affect the following entities, some of which may be small entities: The owner or operators of vessels intending to enter, transit through, anchor in, or remain within the regulated area during the enforcement period. For the reasons discussed in Regulatory Planning and Review section above, this rule will not have a significant economic impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in E.O. 13132.

Also, this proposed rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves special local regulation issued in conjunction with a regatta or marine parade. This rule is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add a temporary § 100.T07–0010 to read as follows:

§ 100.T07–0010 Special Local Regulations; Bucksport/Southeastern Drag Boat Summer Extravaganza, Atlantic Intracoastal Waterway, Bucksport, SC.

(a) *Regulated area.* All waters of the Atlantic Intracoastal Waterway encompassed by a line connecting the following points: Point 1 in position 33°39′13″ N., 079°05′36″ W.; thence west to point 2 in position 33°39′17″ N., 079°05′46″ W.; thence south to point 3 in position 33°38′53″ N., 079°05′39″ W.; thence east to point 4 in position 33°38′54″ N., 079°05′31″ W.; thence north back to point 1. All coordinates are North American Datum 1983.

(b) *Definition.* As used in this section, "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area, except persons and vessels participating in Bucksport/Southeastern Drag Boat Summer Extravaganza or serving as safety vessels. Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740–7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(2) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement date.* This rule will be enforced from 12 p.m. until 7 p.m. daily on July 9 and July 10, 2016.

Dated: March 29, 2016.

G.L. Tomasulo,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2016–07891 Filed 4–5–16; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 16–303; MB Docket No. 16–74; RM–11763]

Radio Broadcasting Services; Raymond, Washington

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the FM Table of Allotments by allotting Channel 300A at Raymond, Washington, as the community's second or third local service. After the filing of the petition, a change of community application was filed for Station KBSG(FM) from Westport, Washington, to Raymond, Washington. Therefore, if the application is granted prior to the issuance of the *Report and Order* in this proceeding, Channel 300A would be a third local service at Raymond, if allotted. A staff engineering analysis indicates that Channel 300A can be allotted to Raymond consistent with the minimum distance separation requirements of the Commission's Rules with a site restriction 4.7 kilometers (3.0 miles) southwest of the community. The reference coordinates are 46–38–49 NL and 123–45–11 WL.

DATES: Comments must be filed on or before May 16, 2016, and reply comments on or before May 31, 2016.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the rule making petitioner and the counter proponent as follows: Peter Gutmann, Esq., Womble Carlyle Sandridge & Rice, LLP, 1200 19th Street NW., 5th Floor, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Notice of Proposed Rule Making,* MB Docket No. 16–74, adopted March 22, 2016, and released March 23, 2016. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

James Bradshaw,

Deputy Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Washington, is amended by adding Raymond, Channel 300A.

[FR Doc. 2016–07888 Filed 4–5–16; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2016–0021]

Federal Motor Vehicle Safety Standards; Occupant Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Denial of petition for rulemaking.

SUMMARY: This document denies a rulemaking petition submitted by Mr. James E. Hofferberth on April 1, 2013. His petition includes two requests: (1) To regulate the performance of supplementary automotive restraint systems that are marketed specifically for pregnant women; and (2) to require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could injure or kill their unborn child," specifically by crushing the unborn baby in a frontal crash. NHTSA is denying the petition to regulate the performance of these systems because the agency does not have sufficient information at this time to state whether there is an additional net safety benefit/disbenefit to be derived from their use or whether one type of device is superior to another. NHTSA is denying the petition for labeling because this would provide advice that, if followed, would threaten the safety of both the mother and the unborn child in a crash.

FOR FURTHER INFORMATION CONTACT:

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For Legal Issues: Mr. John D. Piazza, Office of Chief Counsel, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, Telephone: (202) 366–2992, Facsimile: (202) 366–3820.

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I. Background

In a letter dated April 1, 2013, Mr. James E. Hofferberth petitioned NHTSA to regulate the performance of supplementary automotive restraint systems for pregnant women and to also require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could injure or kill their unborn child." This is the petitioner's second request for rulemaking regarding the safety of seat belts for pregnant women.

A. Past Petition for Rulemaking

In 2005, NHTSA received a petition for rulemaking from this same petitioner, Mr. James E. Hofferberth, requesting that the agency initiate rulemaking to require an advisory placard warning occupants that seat belts should not be worn by pregnant women. On March 23, 2006, NHTSA published a **Federal Register** notice (71 FR 14675) denying that petition because the requested warning label would provide advice that, if followed, would threaten the safety of both the mother and the unborn child in a crash.

B. Agency Position: Pregnant Women Should Wear Their Seat Belts

NHTSA recommends that pregnant women wear their seat belts, as does the American College of Obstetricians and Gynecologists (ACOG).[1] NHTSA publishes a flyer[2] developed in conjunction with ACOG and the National Healthy Babies Coalition that addresses this topic. The flyer describes the proper way for a pregnant woman to position her seat and to wear both the shoulder and lap belt portion of her seat belt, and it also explains that pregnant women should wear their seat belts even in vehicles equipped with air bags.

The safety benefits to pregnant women from wearing seat belts are supported by a research study,[3] which concluded that "[p]roper restraint use, with and without air bag deployment, generally leads to acceptable fetal outcomes in lower severity crashes, while it does not affect fetal outcome in high-severity crashes." The study concluded that "compared to properly restrained pregnant occupants, improperly restrained occupants have a higher risk of adverse fetal outcome in lower severity crashes." It is also recommended that all pregnant women seek medical attention after a car crash regardless of the severity of maternal injury. NHTSA and other experts agree that the best way to protect an unborn child is to protect the mother.[4]

C. Pregnant Women in Motor Vehicle Crashes

The agency conducted an extensive review in its analysis of the petition. This included a review of technical literature, including a study by the University of Michigan Transportation Research Institute (UMTRI), as well as the papers cited by the petitioner. The agency also conducted a full review of the NHTSA field data repositories for evidence of supplementary automotive restraints causing harm to pregnant women in motor vehicle crashes (MVCs). The agency's findings are provided in the following sections of this notice, and they reaffirm the position stated in the 2006 denial notice.

1. Past Studies

NHTSA has sponsored research studying and demonstrating the effectiveness of properly adjusted restraint systems for pregnant women from as early as 1971,[5] when seat belts composed of both a lap and shoulder portion were not as prevalent as they are today. Other research, independent of NHTSA, has also been conducted, and both biomedical research and restraint technologies have advanced over time. For example, a 1998 paper written by researchers at UMTRI explains that the unborn baby is protected by amniotic fluid, which isolates the unborn baby by acting as a shock absorber.[6] This amniotic fluid is what naturally resists the forces from the lap portion of a seat belt, and it prevents the belt from penetrating through the unborn baby's body. Mr. Hofferberth's petition claims that the belt penetrates through the unborn baby's body.

More recently, a 2008 paper written by these same researchers at UMTRI[7] summarized a study in which in-depth investigations of MVCs involving pregnant women were conducted, with a focus on determining how restraint conditions and specific crash characteristics had affected the outcome of the unborn baby. Studies conducted up to this point generally did not include complete and accurate information about crash severity and restraint use, or they emphasized crashes with adverse outcomes for the unborn babies in order to illustrate unusual and/or severe injuries. By including crashes with both positive and adverse outcomes for the unborn baby and also studying both belted and unbelted pregnant women, this study provided medical practitioners and safety engineers more of a comprehensive, quantitative analysis for giving advice to pregnant women and improving the design of vehicle restraints.

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[1] American College of Obstetricians and Gynecologists. "Car Safety for You and Your Baby, Frequently Asked Questions: FAQ018, Pregnancy," August 2011, *http://www.acog.org/~/media/For%20Patients/faq018.pdf?dmc=1&ts=20130603T1624145840.*

[2] NHTSA, The Pregnant Woman's Guide to Buckling Up, Your Top 5 Seat Belt Questions Answered, March 2010, *http://www.trafficsafetymarketing.gov/newtsm/tk-bua/PregnantWomenSeatBeltFlyer.pdf.*

[3] Klinich, K. D., Schneidier, L. W., Moore, J. L., Pearlman, M. D., entitled "Investigations of Crashes Involving Pregnant Occupants," dated 1999. This work was supported by General Motors Corporation, pursuant to an agreement with the U.S. Department of Transportation.

[4] Duma, S., Moorcroft, D., Stitzel, J., Duma, G., entitled "A Computational Model of the Pregnant Occupant: Effects of Restraint Usage and Occupant Position in Fetal Injury Risk," published June 2005 in the Proceedings of the 19th International Technical Conference on the Enhanced Safety of Vehicles.

[5] King, A. I., Crosby, W. M., Stout, L. C., Eppinger, R. H., entitled "Effects of Lap Belt and Three-Point Restraints on Pregnant Baboons Subjected to Deceleration," published in 1971 in the 15th Stapp Crash Conference Proceedings and the Society of Automotive Engineers as paper #710850.

[6] Klinich, K. D., Schneidier, L. W., Moore, J. L., Pearlman, M. D., entitled "Injuries to Pregnant Occupants in Automotive Crashes," published October 1998 in the 42nd Annual Proceedings of the Association for the Advancement of Automotive Medicine.

[7] Klinich, K. D., Flannagan, C. A., Rupp, J. D., et al, entitled, "Fetal outcome in motor-vehicle crashes: effects of crash characteristics and maternal restraint," published April 2008 in the American Journal of Obstetrics & Gynecology.

The 57 investigated cases all involved women of at least 20 weeks gestation who were involved in a motor vehicle crash that was not a rollover and who agreed to participate. Natural spontaneous pregnancy loss before 20 weeks of gestation being not uncommon, which made association of fetal loss so early in pregnancy with an MVC questionable, and the difficulty in determining injury causation to occupants during a rollover event[8] resulted in cases with these two factors being excluded. Case subject interviews and examinations of physical evidence were used to determine seat belt use, and estimated change in velocity (delta-V) from a crash reconstruction program was used to determine crash severity. The outcome of the unborn baby was studied for a period of one month after the crash took place, and these outcomes were classified as either good, minor complications, major complications, or fetal loss. Injuries to the mothers were classified using the Injury Severity Score (ISS), excluding injuries to the placenta or uterus, and these scores were used to classify the mothers' injuries as either nonexistent, minor, moderate, or major. Maternal death was also tracked, regardless of the mother's ISS. Restraints were classified as either proper (3-point belt or 3-point belt plus air bag) or improper (unrestrained, air bag only, and shoulder belt only with air bag, and shoulder belt only without air bag).[9]

The database created by this study became the largest collection of MVCs involving pregnant women including detailed quantitative information about both the crash event and the outcome for the unborn baby, with a focus on crashes with both positive and negative fetal outcomes. The seat belt usage rate in the database was reported as 72 percent,[10] and the study results showed a positive effect on fetal outcome from the mother's proper use of a seat belt during a crash. The statistical risk curves from this study's data analysis "indicate[d] that an 84 percent reduction in risk of adverse fetal outcome is obtained by properly wearing a seatbelt. On the basis of this relative risk and an overall belt use rate of 80 percent, unbelted pregnant women sustain an estimated 62 percent of all fetal losses in motor vehicle crashes . . . Crash severity is the factor most strongly associated with fetal outcome . . . Claims that restraints cause adverse fetal outcomes cannot be substantiated without reliable information on crash severity . . . [M]aternal injury is predictive of fetal outcome, and proper restraint use reduces maternal injury severity."

2. Available Field Data

(a) Data Sources

To analyze the claims in the petition, the agency studied crashes involving pregnant women in the applicable NHTSA data repositories: Artemis,[11] the Fatality Analysis Reporting System (FARS),[12] the National Automotive Sampling System (NASS) Crashworthiness Data System (CDS),[13] and the Special Crash Investigations (SCI) program.[14] Artemis does not currently contain any entries related to complaints or reported injuries resulting from the use of supplemental restraint devices. Although FARS does capture information about fetal demise, its fetal demise data-capturing capabilities are limited because it utilizes the American National Standards Institute (ANSI) definition[15] of a person as "any living human . . . [A] fetus is considered to be part of a pregnant woman rather than a separate individual."[16] Hence, FARS only captures information about fetal demise if someone else involved in the crash also expired. NASS CDS and SCI cases were also consulted for the following analysis. Though the sample of pregnant women in NASS CDS is relatively small, it is an appropriate and applicable source of data to explore the crash risks for this cohort because it is from a nationally representative sample.[17] SCI cases are intended to provide an engineering perspective on anecdotal data, examining special crash circumstances or outcomes. As discussed below, an examination of NASS CDS and SCI data reaffirmed NHTSA's current position that pregnant women should wear a seat belt.

(b) NASS CDS Data

NASS CDS started tracking fetal demise in 2006. The sampling is designed in such a way that it is possible to use the data to compute estimates representative of the entire country through application of a multiplier (case weight) to each NASS CDS case.[18] During this six-year time period there was a weighted estimate of 18,859,898 occupants of passenger vehicles involved in crashes qualifying as NASS CDS cases across the United States. Of these occupants, 0.6 percent [112,341/18,859,898] were pregnant women. The maternal fatality rate for this data set was 0.22 percent [245/112,341]. Where seat belt use was known, 85.0 percent of the pregnant women were reportedly wearing a seat belt and 15.0 percent were not.[19] Of the pregnant women reported to be wearing a seat belt, 99.7 percent [87,065/87,365] did not suffer a uterine or placental injury.

The weighted estimate of 112,341 pregnant women was derived from 439 unweighted cases. Twenty-four of these 439 cases were coded as involving the death of an unborn child. However, the agency believes that four of these cases were miscoded with respect to fetal demise.[20] In addition, one of the twenty-four cases involved a crash for which a NASS investigator inspection of the vehicle was not permitted due to a pending legal case.[21] These five cases were excluded from the data set used for the analysis, and the 19 remaining cases correspond to a weighted estimate of 2,460 pregnant women who lost their unborn baby following a crash. The weighted data show that 2.2 percent of pregnant women lost an unborn child after being involved in a crash during this 6 year period, and 99.9 percent [87,251/87,365] of those known to be wearing a seat belt did not lose an unborn child due to a seat belt-caused uterine or placental injury.

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[8] Excluding rollover events may have created a slight bias in the database. The paper states that ". . . rollovers account for only 2 percent of all crashes annually in the United States. The effect of this exclusion is therefore expected to have minimal impact on the study findings."

[9] None of the maternal occupants in the cases studied wore only a lap belt.

[10] This statistic was reported in the 2008 Klinich paper, referring to the 2005 NHTSA report, DOT HS 810 623, Traffic Safety Facts 2005. A more specific comparison would be the seat belt use rate for women of likely childbearing age.

[11] Artemis is the agency's repository of motor vehicle and motor vehicle equipment defects. It contains consumer complaints and manufacturer early warning and reporting information, recalls, and safety defect investigations.

[12] FARS is a census of fatal motor vehicle crashes from 1975 to the present from the fifty States, the District of Columbia, and Puerto Rico. To qualify as a FARS case, the death of either a non-motorist or a motorist must occur within 30 days of the crash and the vehicle must be traveling on a trafficway customarily open to the public.

[13] NASS CDS is a database containing a probability sample of all police reported crashes in the U.S. Cases are chosen from all police reported crashes involving a harmful event (property damage and/or personal injury) resulting from a crash and involving at least one towed passenger car, light truck, or van in transport on a trafficway.

[14] SCI cases are selective, highly detailed and in-depth crash investigations using data from police and insurance reports as well as medical records, site and vehicle inspections, and interviews.

[15] DOT HS 811 694, 2011 Fatality Analysis Reporting System (FARS) and National Automotive Sampling System (NASS) General Estimates System (GES) Coding and Validation Manual, Page 5, Section 103.1, published 2012.

[16] Section 2.1.1 of standard ANSI D16.1–2007, the Manual on Classification of Motor Vehicle Traffic Accidents, Seventh Edition, prepared by the D16 Committee on Classification of Motor Vehicle Traffic Accidents under the direction of the Association of Transportation Safety Information Professionals of the National Safety Council Highway Traffic Safety Section and approved on August 2, 2007 by the American National Standards Institute, Inc. Board of Standards Review.

[17] In 2009, NASS CDS started collecting only partial occupant assessment records and no occupant injury records for vehicles more than 10 model years old. Information about occupant seat belt usage, a woman's pregnancy and the status of a fetus comes solely from a police report for these vehicles more than 10 model years old, and typically police reports subscribe to Section 2.1.1 of standard ANSI D16.1–2007 in regards to the fetus being considered an occupant.

[18] DOT HS 811 675, National Automotive Sampling System—Crashworthiness Data System 2011 Analytical User's Manual, Page 6, Section 3, "The Sampling System and Sample Design," published October 2012.

[19] The seat belt wearing status of 8.5 percent [9,533/112,341] of the pregnant females was reported as unknown. It should also be noted that those coded as wearing a seat belt were not necessarily wearing the seat belt correctly.

Due to the small number of cases involving pregnant women who lost an unborn child after a crash and variation in the NASS CDS case weight factors applied to small numbers,[22] the following statistics associated with the data are provided for illustration only. The known belt use rate[23] for the fetal demise data set was 85.1 percent [2,094/2,460], which is nearly identical to the known belt use rate for the data set of 112,341 pregnant women previously described. The maternal fatality rate was 9.1 percent [223/2,460]. This is more than forty times the maternal fatality rate for the data set of all pregnant women (0.22 percent). The rate of placental injury in this data set was 42.4 percent [155/366] for the unbelted pregnant women, but only 5.4 percent [114/2,094] for the belted. Placental injuries sustained by the unbelted women were caused by contact with either the steering wheel or the ground after ejection from the vehicle. The maternal fatality rate for the unbelted occupants with fetal demise was 30.3 percent [111/366] but only 5.3 percent [112/2,094] for the belted occupants. For belted occupants, 94.6 percent [1,980/2,094] of the pregnant women who lost an unborn child did not suffer a uterine or placental injury from the seat belt.[24] In other words, 94.6 percent of the time when a pregnant woman was wearing her seat belt and her unborn baby died in an MVC, the seat belt did not injure her uterus or placenta. Moreover, NASS CDS, a nationally representative sample, contains few cases of fetal demise, illustrating the rarity of this event.

(c) NHTSA Case Studies

In order to be consistent with previous research in studying the deaths of unborn babies in frontal crashes, NHTSA aligned the NASS CDS data with that of the 2008 UMTRI study. This eliminated 18 of the 19 cases from the 2006–2011 NASS CDS dataset involving the death of an unborn child: Eight cases[25] because they involved pregnant women in their first trimester, four cases[26] because they involved a rollover or other multi-event crash scenario, and six cases[27] because their principal direction of force (PDOF) did not indicate a frontal collision.[28] This left one case that was consistent with the UMTRI study's criteria. In addition, the agency included one case from the multi-event crash group in which the first event was a frontal impact and the second event was relatively minor. These cases are discussed below. This exercise demonstrated both the rarity of fetal demise in a vehicle crash as well as the complex nature of injury causation for a pregnant woman, further supporting the agency's position that pregnant women should wear a seat belt.

Case 2006–78–71

The one NASS CDS case that matched the 2008 UMTRI study criteria was case 2006–78–71. In this case, two vehicles were involved in a head-on collision. The 32 year old driver of the second vehicle, a 1993 Mazda 626 equipped with air bags, was 9 months pregnant and not wearing a seat belt. She was 150 cm tall and weighed 64 kg, with a Body Mass Index (BMI)[29] of 28.4. Crash reconstruction estimated the Delta-V to be 34 km/h longitudinally, and the NASS CDS investigator noted that there was no steering wheel rim/spoke deformation. The driver air bag did not deploy in this crash. The driver's most severe injury was an AIS 5[30] complex uterus laceration, judged to have certainly[31] been caused by direct contact with the steering wheel. She also had an AIS 2 minor mesentery laceration and an AIS 1 abrasion to her right hip, both also certain to have been caused by direct contact with the steering wheel. She was discharged from the hospital after 12 days, and medical records confirmed the death of the unborn baby.

Case 2008–09–26

This multi-event case from NASS CDS was also the focus of a NHTSA SCI investigation due to the concern that placental abruption was possibly caused by the seat belt. In this case, the vehicle containing the 40 year old pregnant woman, a 2006 Mercedes Benz E350, collided with a 2005 Ford Explorer Sport Trac attempting to make a left-hand turn. Crash reconstruction estimated the pregnant woman's vehicle to have a longitudinal Delta-V of 37 km/h. The Mercedes struck the Ford forward of its center of gravity, causing the Ford to quickly rotate and strike the Mercedes in a side-slap impact. The pregnant woman was seated in the first row passenger seat and was wearing her seat belt, though it is unknown whether the seat belt was worn correctly. She was 165 cm tall and weighed 91 kg at the time of the crash, corresponding to a BMI of 33.4, placing her in the obese category.

The pregnant woman had 11 injuries with AIS scores ranging from 1 to 3. The most critical six were determined to have possibly resulted from contact with the driver and the center console during the side-slap, the most severe being an AIS 3 cerebrum subarachnoid hemorrhage. These injuries did not occur in the uterine area, and they were not directly related to the death of the unborn child. Injury number 7 of 11 was an AIS 3 lower placental abruption,[32] possibly caused by the belt webbing/buckle. The only other injury to the pregnant woman's uterine area was an abdominal skin contusion with the precise location unknown, possibly caused by the belt webbing/buckle.

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[20] Cases 2007–43–199, 2008–43–24, 2009–43–188, and 2010–78–43 were flagged in the database as involving fetal demise, but they were excluded because examination of the case files provided convincing evidence that these were likely miscoded.

[21] Because both vehicle occupants perished in the crash, occupant interviews could not be conducted.

[22] The weight factor for the remaining 19 cases ranges from 8.35 to 594.

[23] Though all of these women did wear a seat belt, not all of them wore their seat belts correctly with the lap belt portion snug and low, across the hips.

[24] Injuries to the mother not caused by a seat belt tended to be from contact to other interior vehicle parts or from other sources such as the striking vehicle. In some cases injury causation could not be determined, and these cases were not included in calculating this value.

[25] NASS CDS cases 2006–47–56, 2006–75–212, 2007–41–1, 2007–48–128, 2007–72–119, 2008–11–21, 2008–75–5, and 2008–75–20.

[26] NASS CDS cases 2006–12–69, 2008–09–26, 2009–74–143, and 2011–13–152.

[27] NASS CDS cases 2006–73–35, 2006–73–106, 2007–76–25, 2008–75–84, 2010–48–127, and 2011–49–15.

[28] In addition to keeping an occupant inside of the vehicle during a rollover or side impact, a seat belt also holds an occupant into the seat during an event which would send an unrestrained occupant forward toward the steering wheel and windshield. It is during these forward motions that the seat belt becomes a potential source of injury to an unborn child, and these forward occupant motions are caused by frontal collisions where the vehicle's PDOF is pushing the car backwards. For this assessment a case was determined to be a frontal collision if the PDOF for the pregnant woman's vehicle was within ±45° of normal to the vehicle's frontal plane.

[29] Centers for Disease Control and Prevention (CDC). Healthy Weight—it's not a diet, it's a lifestyle!. September 13, 2011. *http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/*.

[30] An AIS 5 is the highest survivable AIS score, with an AIS 6 indicating that a particular injury was unsurvivable.

[31] NASS CDS investigators must assign a confidence level to all injury sources. The choices for these levels in descending order of investigator confidence are "Certain," "Probable," "Possible," and "Unknown."

While the crash was assigned to NHTSA's SCI team, the SCI investigators were not able to conduct interviews or inspect the vehicle until approximately 6 months after the crash. Though it was certain that the pregnant woman had been wearing her seat belt, investigators were not able to conclusively determine whether or not she had been wearing it correctly.

II. Current Petition

Mr. Hofferberth petitions for two rulemakings. First, he requests that the agency initiate a rulemaking for Supplementary Automotive Restraint Systems for Pregnant Women. Second, the petitioner requests that the agency initiate rulemaking to require the warning of pregnant women that the seat belts could injure or kill their unborn children.[33] The petition includes a proposed performance specification and validation test procedure for supplementary restraint systems for pregnant women, including labelling, fit, position retention, strength, and stiffness requirements, as well as a design for a test platform. The petition also includes an unpublished report, "Prevention of Fetal Injury in Motor Vehicle Crashes," written by the petitioner.[34] The petitioner makes a number of factual assertions and arguments regarding his belief that the lap belt presents a significant hazard for the unborn child of a pregnant woman.

The petitioner, in both his letter and the attached report, states his beliefs that unborn babies are in danger of being crushed by the lap belt portion of a seat belt during a frontal collision and that seat belts are not appropriate for use by pregnant women. He cites research that he asserts shows that the lap belt portion of the restraint system has been implicated in causing specific trauma to the placenta and unborn child in relatively minor vehicular accidents. He also cites other research that he argues shows a high rate of fetal and placental injury and asserts that research shows that the fetus of a pregnant woman is approximately five times more likely to receive serious injury than a 0–1 year old child using a supplementary infant or child restraint riding in the same car.

The petitioner also states that there are many supplementary restraint products on the market for pregnant women, which are not all equally effective and in some cases dangerous. The petitioner presents depictions and makes assertions regarding the effectiveness of several of these restraints, including a restraint which he patented.

III. NHTSA's Consideration of the Petition

A. General Principles

Motor vehicle safety standards must be practicable, meet the need for motor vehicle safety, and be stated in objective terms. 49 U.S.C. 30111(a). Petitions for rulemaking are governed by 49 CFR part 552. Pursuant to Part 552, the agency conducts a technical review of the petition, which may consist of an analysis of the material submitted, together with information already in possession of the agency. In deciding whether to grant or deny a petition, the agency considers this technical review as well as appropriate factors, which may include, among others, allocation of agency resources and agency priorities.

B. Analysis of the Petition

The agency's technical review of the petition had several main parts. First, the agency reviewed the petition and the sources it cited before conducting a comprehensive literature review, which included material from the early 1970s through the present. Additionally, the agency, as described above, conducted an updated review of crash data available from the NHTSA field databases, including NASS CDS. The agency considered all of the information contained in the petition, and for the reasons stated below, the agency is denying the petition.

The first part of Mr. Hofferberth's petition asks that NHTSA regulate the performance of supplementary automotive restraint systems for pregnant women. In assessing this aspect of the petition, NHTSA first attempted to quantify the safety problem, *i.e.,* whether there is an unreasonable risk of death or injury to pregnant women or to unborn children in a belted condition when exposed to a crash that would lead NHTSA to propose a performance requirement for supplemental restraint devices. The agency could not establish this through the technical review of the submitted petition materials.

For example, the petitioner asserts that unborn babies are in danger of being crushed by the lap belt portion of a seat belt during a frontal collision and that seat belts are not appropriate for use by pregnant women. However, the comprehensive UMTRI study showed that a pregnant woman's proper use of a seat belt has a positive effect on fetal outcome in a crash: "an 84 percent reduction in risk of adverse fetal outcome is obtained by properly wearing a seatbelt. On the basis of this relative risk and an overall belt use rate of 80 percent, unbelted pregnant occupants sustain an estimated 62 percent of all fetal losses in motor vehicle crashes." In addition, the amniotic fluid is capable of resisting the forces from the lap portion of a seat belt, and can aid in preventing the belt from penetrating through the unborn baby's body.

Similarly, the petitioner asserts that the lap belt portion of the restraint system causes fetal trauma in relatively minor crashes. However, as discussed above, a study[35] found that "[p]roper restraint use, with and without air bag deployment, generally leads to acceptable fetal outcomes in lower severity crashes," and went on to conclude that "compared to properly restrained pregnant occupants, improperly restrained occupants have a higher risk of adverse fetal outcome in lower severity crashes."

Additionally, the agency performed an updated review of crash data available from the NHTSA field databases, including NASS CDS. Although the petitioner asserts that unborn babies are in danger of being crushed by the lap belt portion of a seat belt and cites research that he argues shows a high rate of fetal and placental injury, the agency found that a low percentage (2.22 percent) of pregnant women lost their child after being exposed to a crash. The detailed review of all fetal demise cases indicated that all but one fell into the exclusion criteria used by UMTRI in their field data analysis. This one case was of an unbelted woman who sustained an AIS 5 complex uterus laceration caused by direct contact with the steering wheel.[36] Additional information regarding the analysis of NHTSA data for placental injury to belted pregnant women and the correlation of fetal mortality with higher crash severity, illustrating the beneficial effects of seat belt use by pregnant women, is provided above in section I.C.2. Accordingly, at this time the analysis of the field data does not indicate a safety need to propose a standard for supplemental restraints for pregnant women.

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[32] The emergency personnel response time could not be determined for this case, though upon arrival at the scene, it was noted that the pregnant woman complained of head, chest, and abdominal pain with vaginal bleeding. She was transported by ground ambulance to a trauma center 10 miles away, where an ultrasound was immediately conducted, and a reduced fetal heartbeat was noted. The pregnant woman then had an emergency caesarian section, about 120 minutes post-crash, and a live 24.2 oz female baby was delivered in critical condition and transported to the Neonatal Intensive Care Unit (NICU). The baby died about 26 hours post-delivery due to premature birth as a consequence of the placental abruption.

[33] As explained above, and discussed in more detail below, this is contrary to NHTSA's considered view and the available evidence which establishes that pregnant women should wear their seat belts.

[34] In this report, the petitioner also states, as a "Recommendation," that NHTSA should update its recommended usage of the lap and shoulder belt by pregnant women to reflect the petitioner's views, as well as research the petitioner cites as supporting his views. Although this request is not a petition for rulemaking, the agency's decision on the petition for a warning label rulemaking is responsive to this suggestion. The petitioner also recommends that NHTSA initiate rulemaking requiring pregnant motor vehicle occupants to use a supplemental restraint system. NHTSA does not have statutory authority for such a rulemaking.

[35] Klinich, K. D., Schneidier, L. W., Moore, J. L., Pearlman, M. D., entitled "Investigations of Crashes Involving Pregnant Occupants," dated 1999. This work was supported by General Motors Corporation, pursuant to an agreement with the U.S. Department of Transportation.

With regard to establishing performance requirements for supplemental restraints, NHTSA does not have sufficient information at this time to state whether there is any additional net safety benefit/disbenefit to be derived from their use or whether one type of device is superior to another. The agency notes that these devices are considered motor vehicle equipment, and manufacturers of these devices are subject to the recall and remedy requirements of the Motor Vehicle Safety Act (49 U.S.C. 30118–30120). To date NHTSA has not seen evidence of these devices causing harm to pregnant women. Artemis, the agency's central repository of data on motor vehicles and motor vehicle equipment defects, does not currently contain entries related to complaints or reported injuries resulting from the use of such devices.

Given the observed correlation between maternal and fetal outcome, the agency believes that improvements in crashworthiness, particularly advancements in occupant restraint systems, will serve to protect pregnant women and their unborn children. NHTSA continues to work towards these improvements through research efforts in the areas of advanced restraints and improvements to the Federal motor vehicle safety standards. The petitioner did not provide any data or testing to support the benefits of supplemental devices or the merits of the proposed test procedure to discriminate between good and bad performance to serve as a basis for such a performance requirement.

The second request in the petition asks that the agency warn pregnant women of the risk from the seat belt through a prominent warning label required in every vehicle. As noted in the **Federal Register** notice denying Mr. Hofferberth's 2005 petition to initiate rulemaking on a similar advisory placard (71 FR 14675), the agency disagrees with the claim that seat belts are hazardous to unborn babies. The agency position regarding the benefits of seat belts for both the mother and the unborn child has not changed since the publication of the 2006 denial notice and is supported, as discussed above, by the agency's review of the technical literature and field data.

As noted above, the agency conducted an extensive literature review and reviewed all sources cited by the petitioner. It is the agency's view that this literature shows that the most effective way to protect the unborn baby is to protect the pregnant woman. Technical studies were discussed in the preceding sections of this notice of decision. Additionally, the agency is not aware of any serious injuries to pregnant women caused by seat belts in non-impact situations, and the aforementioned 2008 Klinich paper showed that "[c]laims that restraints cause adverse fetal outcomes cannot be substantiated without reliable information on crash severity."

The agency's field data analysis shows, among other things, that seat belt-caused uterine or placental injuries during crashes are extremely rare (0.1 percent of cases) and that seat belt use dramatically reduces the risk of dying in a crash for both pregnant women and unborn children. Additional information regarding the agency's field data analysis is provided above in section I.C.2.

Accordingly, for the reasons stated above, the petition is denied.

IV. Future Plans

A study showed that despite NHTSA recommending specific seat belt best practices for pregnant women, approximately one quarter of the pregnant women being studied did not follow the recommendation, and nearly two thirds of them had not received the information.[37] When asked about the effects of seat belts on their unborn babies during a motor vehicle collision, 34.0 percent of these same pregnant women were not sure, and another 10.7 percent believed that the seat belts would actually cause harm.[38] A study supported by the Federal Highway Administration reported that "[e]ducational level is a factor predicting seatbelt use. Among women with less than a high school education, 41 percent did not employ seatbelt restraints as compared with 18.8 percent who were high school graduates . . . [P]regnant women of lower educational level and socioeconomic status are at particular risk for failing to correctly employ seatbelts during pregnancy."[39]

Another recent study supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, of the National Institutes of Health, reported that even though most pregnant women wear seat belts, those who do are not necessarily wearing them correctly. Additionally, this report states that despite ACOG's recommendation that all pregnant women receive prenatal seat belt counseling, not all women receive it. It also suggests that increased educational efforts emphasizing not only the use of seat belts but also their proper placement would be appropriate.[40]

The agency believes that it is very important to convey the importance of proper seat belt use to pregnant women. As indicated by the aforementioned studies, a large percentage of pregnant women are not following the current recommendations; therefore, NHTSA has decided to increase outreach efforts in this area. NHTSA currently posts the agency's official brochure, *If You are Pregnant: Seat Belt Recommendations for Drivers and Passengers,* on all official Web sites. It is a popular download from TrafficSafetyMarketing.gov,[41] the Web site for all NHTSA partners to find official publicity material. To increase the dissemination of this brochure, the agency plans to add it to the social networking outreach rotation of messages distributed through outlets such as Facebook and Twitter, and its content has been more prominently featured on Parents Central.[42] Proper seat belt use and seat positioning for pregnant women will also be the focus of an upcoming Safety in Numbers feature on the NHTSA Web site.

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[36] Case 2008–09–26 did involve a pregnant woman who experienced a placental abruption, but investigators were not able to determine whether the occupant had been wearing the belt correctly.

[37] McGwin Jr., G., Willey, P., Ware, A., et al., entitled, "A Focused Educational Intervention Can Promote the Proper Application of Seat Belts during Pregnancy," published May 2004 in The Journal of Trauma Injury, Infection, and Critical Care.

[38] McGwin, Jr., G., Russell, S., Rux, R., et al., entitled, "Knowledge, Beliefs, and Practices Concerning Seat Belt Use During Pregnancy," published March 2004 in The Journal of Trauma Injury, Infection, and Critical Care.

[39] Taylor, A. J., McGwin Jr., G., Sharp, C. E., et al., entitled, "Seatbelt Use During Pregnancy: A Comparison of Women in Two Prenatal Care Settings," published June 2005 in the Maternal and Child Health Journal, Vol. 9, No. 2.

[40] Vladutiu, C. J., Weiss, H. B., entitled, "Motor Vehicle Safety During Pregnancy," published October 2011 in the American Journal of Lifestyle Medicine, Vol. 6, No. 3.

[41] *http://www.trafficsafetymarketing.gov/CAMPAIGNS/Seat+Belts/Buckle+Up+America/Thanksgiving+Weekend/Pregnant+Women's+Guide+To+Buckling+Up.*

V. Conclusion

After carefully considering the safety need for the requested rulemaking and supporting information and in accordance with 49 CFR part 552, NHTSA hereby denies Mr. James E. Hofferberth's April 1, 2013 petition to regulate the performance of supplementary automotive restraint systems that are marketed specifically for pregnant women and to require prominent warning labels in all vehicles with the intent of informing pregnant women that "seat belts could injure or kill their unborn child." Research and real-world data show the substantial benefits of seat belt use for both pregnant women and unborn children, and the agency recommends that all pregnant women wear properly adjusted seat belts.

The agency takes the safety of pregnant women very seriously and has already begun to increase awareness and educational efforts related to the proper use of seat belts while continuing to monitor the data trends surrounding this issue.

In accordance with 49 CFR part 552, this concludes the agency's review of the petition.

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30162; delegation of authority at 49 CFR 1.95.

Issued in Washington, DC, on: March 31, 2016 under authority delegated in 49 CFR 1.95.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2016–07827 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–59–P

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[42] *http://www.safercar.gov/parents/SeatBelts/Pregnancy-Seat-Belt-Safety.htm.*

Notices

Federal Register
Vol. 81, No. 66
Wednesday, April 6, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Economic Research Service

Notice of Intent To Request New Information Collection

AGENCY: Economic Research Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the Economic Research Service's intention to request approval for a new information collection for a Pilot Survey on Food Acquisition among American Households.

DATES: Written comments must be received by June 6, 2016 to be assured of consideration.

ADDRESSES: Address all comments concerning this notice to John Kirlin, Food Assistance Branch, Food Economics Division, Economic Research Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Mailstop 1800, Washington, DC 20250–0002. Comments may also be submitted via email to *JKIRLIN@ers.usda.gov.*

FOR FURTHER INFORMATION CONTACT: John Kirlin, *JKIRLIN@ers.usda.gov. Tel.* 202–694–5398.

SUPPLEMENTARY INFORMATION:

Title: National Food Study Pilot.

OMB Number: To be assigned by OMB.

Expiration Date: Three years from the date of approval.

Type of Request: New information collection.

Abstract: The National Food Study (NFS) pilot will be conducted over a four-month period from October 2016 through January 2017. The survey will collect nationally representative data from 500 households, including 150 households participating in the Supplemental Nutrition Assistance Program (SNAP, formerly the Food Stamp Program). Each eligible household will be asked to record their food acquisitions for each household member over a 7-day period.

The U.S. Department of Agriculture collected similar data in 2012–2013 with the National Household Food Acquisition and Purchase Survey (FoodAPS, OMB Control Number 0536–0068). Participating household members in that survey used food booklets and a hand-held scanner to record information about all food acquisitions during a 7-day period. There is evidence in the FoodAPS data of some drop-off in the frequency of reported food acquisitions toward the end of the 7-day reporting periods. FoodAPS was a nationally representative survey with over-sampling of households participating in the Supplemental Nutrition Assistance Program (SNAP) and non-SNAP households with low incomes.

The main objective of the NFS pilot is to test an alternative method of collecting data on the foods acquired by American households that leads to more complete and accurate information about patterns of food acquisitions. Other objectives are to explore the feasibility of expanding the population of interest to include households receiving benefits from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and to collect more complete and accurate information on income. Data will be collected from households in nine states.

The sample will be selected from an address-based sampling frame. A total of 2,154 households from 12 Primary Sampling Units (PSUs) in nine states will receive a letter requesting their participation in the study. The pilot will also test the effectiveness of using WIC and SNAP administrative data at identifying SNAP and WIC participants.

The NFS pilot data collection begins by screening households via an in-person interview to determine eligibility and identifying a primary respondent (person who does the majority of the grocery shopping and cooking for the household) within eligible households. Next, an in-person initial interview is completed with the primary respondent. Then, all members of the household age 11 years and older are asked to access a web-based system daily to report food or drinks obtained during their assigned data collection week. Upon completion of the week-long data collection, a final in-person interview is completed with the primary respondent. To determine measurement error, immediately after the final interview, a follow-up re-interview will be conducted with two household members about their last two reporting days and to probe for missing information.

Food obtained by household members includes food purchased or obtained for free and brought into the home as well as food purchased or acquired for free outside of the home. Information to be collected about each food event will include place name and type, location, date, total cost, and method(s) of payment. Food item information to be collected will include an item descriptor, quantity acquired, unit price, and use of coupons or store loyalty cards that reduce actual cost. Participants also will be asked to upload photos of receipts. Participants will receive reminder email messages or text messages throughout the week if they do not report acquisitions for a day. If needed, households will be provided electronic equipment for the duration of their data collection period to assist them in accessing the web instrument.

Recruited households will receive $50 upon completion of the initial interview. Households will accumulate a $3 per day credit for each eligible household member whose food purchase behavior (including affirmation of no acquisitions) is recorded in the web system for that day, and a bonus of $50 for households whose members record food acquisitions for all 7 days and that complete the final interview. Finally, $5 will be provided to the household if members complete the income questions online.

All data collection instruments will ask only the most pertinent information, and the web-based system will be as respondent- and user-friendly as possible. Responses are voluntary and confidential. The instruments and procedures will be pretested prior to the finalization.

Responses from the National Food Study pilot will be combined for statistical purposes and reported only in aggregate or statistical form. A final report summarizing the findings will include an evaluation on the accuracy of administrative data used to select WIC and SNAP households as well as an evaluation of the feasibility of the web-based data collection system. Because this is a pilot test of a new data collection mode, there are no plans to make the collected data available to the public. The data will be analyzed and used as the Agency makes plans for a full-scale data collection at a future date.

Authority: These data will be collected under the authority of 7 U.S.C. 2204(a). ERS will comply with OMB Implementation Guidance, "Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)", 72 FR 33362, June 15, 2007. Respondent information will be protected under the CIPSEA and the 7 U.S.C. 2276.

Affected Public: Respondent groups identified include: SNAP households, WIC households, and non-SNAP and non-WIC households.

Estimated Number of Respondents: The number of respondents is 2,154 households, of which 580 are expected to include SNAP participants. This includes: (i) Advance Letter: 2,154 households; (ii) Screener: 1,551 households (assumes a10% vacancy rate for SNAP households, a 15% vacancy rate for non-SNAP households, and a 72% response rate); (iii) Initial Interview: 593 responding households and 958 non-responding or non-eligible households composed of 540 households screened out due to unfamiliarity with smartphone or internet technology (assumes 45% of SNAP and 40% of non-SNAP households), 248 households screened out due to high income (assumes 21% of remaining non-SNAP households), and 170 households declining to participate in the study (assumes completion rates of 85% for eligible SNAP households and 75% for eligible non-SNAP households); (iv) Final Interview: 534 households (assumes a 90% response rate); and (v) Respondent Feedback Form: 507 households (assumes a 95% response rate). Data collection at the individual level contributes to household-level burden estimates, and the number of individual respondents is the number of households completing the Initial Interview (593) times estimated average household size (2.4), or 1424 individuals. The number of individual respondents is: (vi) Training: 1424 respondents (assumes an average of 2.4 individuals per household); It is assumed that 10% of households decide not to continue with the survey after the training, leaving 534 households and 1282 individuals. (vii) Income Worksheet: 999 respondents (assumes an 85% response rate for SNAP households and a 75% response rate for non-SNAP households); (viii) Food Reporting System and Meals and Snack Form: 1026 respondents (assumes an 80% response rate); and (ix) Re-interview: 961 respondents (assumes a 90% response rate, 2 persons per household).

Estimated Number of Responses per Respondent: All respondents 11 years and older who access the web once daily, will respond seven times. Respondents who complete the screener, initial, and final interviews will respond an additional three times. Respondents completing the re-interview will provide one additional response.

Estimated Time per Response: Reading the advance letter and completing the screener, initial, final, and feedback instruments will average 1.33 hours per household (or primary respondent). Individuals (including the primary respondent) who access the web to receive training, provide information on food acquisitions, income, and meals/snacks, and complete the re-interview will average 1.97 hours per respondent.

Estimated Total Burden on Respondents: 6,394 hours. See table for details.

REPORTING BURDEN

Instrument	Sample size	Freq	Responses				Non-response/Not eligible				Total burden hours
			Resp. count	Freq × count	Min./Resp.	Burden hours	Non-resp. count	Freq × count	Min./Resp.	Burden hours	
Advance letters	2154	1	2154	2154	3	108	0	0	0	0	108
Household-level Data Collection:											
Household Screener	2154	1	1551	1551	12	310	603	603	5	50	360
Initial Household Interview	1551	1	593	593	30	297	958	958	1.8	29	326
Final Household Interview	593	1	534	534	30	267	59	59	3	3	270
Respondent Feedback Form	534	1	507	507	5	42	27	27	3	1	44
Total Responding Burden—HH	2154	....	2154	....	....	1024	....	....	....	83	1107
Individual-level Data Collection:											
Training	1424	1	1424	1424	45	1068	0	0	0	0	1068
Income Worksheet—Individual	1282	1	999	999	15	250	283	283	3	14	264
Food Reporting System	1282	7	1026	7182	25	2993	256	1792	3	90	3083
Meals and Snacks Form	1282	7	1026	7182	3	359	256	1792	1	30	389
Re-interview	1068	1	961	961	30	481	107	107	1	2	482
Total Responding Burden—Ind.	1424	....	1424	....	....	5148	301	....	....	136	5286
Total Responding Burden	2154	....	2154	....	....	6175	....	....	....	219	6394

Estimates of burden hours have been rounded.

Comments: Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to John Kirlin, Resource and Rural Economics Division, Economic Research Service, U.S. Department of Agriculture, 1400 Independence Ave. SW., Mailstop 1800, Washington, DC 20250–1800. Comments may also be submitted via fax to the attention of John Kirlin at

202–694–5661—or via email to *JKIRLIN@ers.usda.gov.* All comments received will be available for public inspection during regular business hours at the same address.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: March 24, 2016.

Mary Bohman,

Administrator, Economic Research Service.

[FR Doc. 2016–07850 Filed 4–5–16; 8:45 am]

BILLING CODE 3410–18–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Information Collection; Comment Request—Report of Disqualification From Participation—Institutions and Responsible Principals/Individuals (FNS–843) and Report of Disqualification From Participation—Individually Disqualified Responsible Principal/Individual or Day Care Home Provider (FNS–844)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and public agencies to comment on a proposed information collection. This collection is an extension, without change, of a currently approved collection for maintaining the National Disqualified List of institutions, day care home providers, and individuals that have been terminated or otherwise disqualified from Child and Adult Care Food Program (CACFP) participation. These federal requirements affect eligibility under the CACFP. The State Agencies are required to enter data as institutions and individuals become disqualified from participating in the CACFP. The collection is the result of a FNS web-based system constructed to update and maintain the list of disqualified institutions and individuals so that no State agency or sponsoring organization may approve any entity on the National Disqualified List to ensure the integrity of the Program.

DATES: Written comments must be received on or before June 6, 2016.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Sarah Smith-Holmes, Director, Program Monitoring and Operational Support Branch, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 630, Alexandria, Virginia 22302. Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comment(s) will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval, and will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Sarah Smith-Holmes (703) 305–2063.

SUPPLEMENTARY INFORMATION:

Title: CACFP National Disqualified List—Forms FNS–843, FNS–844.

Form Number: FNS–843 and FNS–844.

OMB Number: 0584–0584.

Expiration Date: August 31, 2016.

Type of Request: Extension, without change, of a currently approved collection.

Abstract: The Food and Nutrition Service administers the Child Nutrition Act of 1966, as amended (42 U.S.C. 1771, *et seq.*). Section 243(c) of Public Law 106–224, the Agricultural Risk Protection Act of 2000, amended section 17(d)(5) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766(d)(5)(E)(i) and (ii)) by requiring the Department of Agriculture to maintain a list of institutions, day care home providers, and individuals that have been terminated or otherwise disqualified from Child and Adult Care Food Program participation. The law also requires the Department to make the list available to State agencies for their use in reviewing applications to participate in the program and to sponsoring organizations to ensure that they do not employ as principals any persons who are disqualified from the program. Forms FNS–843 and FNS–844 are used to collect and maintain this data. This statutory mandate has been incorporated into § 226.6(c)(7) of the Program regulations. In addition, the recordkeeping burden associated with maintaining documentation related to institutions and providers terminated for cause at the State agency level is captured under the Information Collection for 7 CFR part 226, Child and Adult Care Food Program OMB Control Number 0584–0055, expiration date September 30, 2016. Therefore, there is no recordkeeping burden associated with this collection.

Affected Public: State Agencies.

Estimated Number of Respondents: 56.

Estimated Number of Responses per Respondent: 28.

Estimated Total Annual Responses: 1,568.

Estimate Time Per Response: .50.

Estimated Total Annual Burden: 784.

Affected public	Instrument	Estimated number of respondents	Number of responses per respondent	Total annual responses	Estimated total hours per response	Estimated total burden
Reporting						
State Agencies	FNS 843	56	6	336	.50	168
State Agencies	FNS 844	56	22	1,232	.50	616
Total Estimated Reporting Burden		56		1,568		784

Dated: March 31, 2016.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2016–07913 Filed 4–5–16; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–849]

Steel Wire Garment Hangers From Taiwan: Rescission of Antidumping Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 6, 2016.

SUMMARY: The Department of Commerce (the "Department") is rescinding the administrative review of the antidumping duty order on steel wire garment hangers from Taiwan for the period of review ("POR"), December 1, 2014, through November 30, 2015.

FOR FURTHER INFORMATION CONTACT: Kenneth Hawkins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone 202.482.6491.

SUPPLEMENTARY INFORMATION:

Background

On February 9, 2016, based on a timely request for review by Petitioners,[1] the Department published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on steel wire garment hangers for six companies, covering the period December 1, 2014, through November 30, 2015.[2] On March 22, 2016, Petitioners withdrew their request for an administrative review of these companies.[3]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review if the party that requested the review withdraws its request within 90 days of the publication of the notice of initiation of the requested review. Petitioners withdrew their request within the 90-day deadline. No other party requested an administrative review of the antidumping duty order. As a result, we are rescinding the administrative review of steel wire garment hangers from Taiwan for the POR.

Assessment

The Department will instruct U.S. Customs and Border Protection ("CBP") to assess antidumping duties on all appropriate entries. Because the Department is rescinding this administrative review in its entirety, the entries to which this administrative review pertained shall be assessed antidumping duties at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). The Department intends to issue appropriate assessment instructions to CBP 15 days after the publication of this notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a final reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: March 31, 2016.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2016–07903 Filed 4–5–16; 8:45 am]

BILLING CODE 3510–DS–P

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[1] M&B Metal Products Company, Inc., Innovative Fabrication LLC/Indy Hanger and US Hanger Company, LLC (collectively "Petitioners").

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 81 FR 6832 (February 9, 2016) ("*Initiation*").

[3] *See* letter from Petitioners, "Re: Third Administrative Review of Steel Wire Garment Hangers from Taiwan—Petitioners' Withdrawal of Review Request," dated March 22, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–037]

Certain Biaxial Integral Geogrid Products From the People's Republic of China: Notice of Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* April 6, 2016.

FOR FURTHER INFORMATION CONTACT: Katie Marksberry, AD/CVD Operations, Office V, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: 202–482–7906.

SUPPLEMENTARY INFORMATION:

Background

On February 8, 2016, the Department of Commerce ("Department") initiated the countervailing duty investigation of certain biaxial integral geogrid products from the People's Republic of China. *See Certain Biaxial Integral Geogrid Products from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 81 FR 7745 (February 16, 2016). Currently, the preliminary determination is due no later than April 13, 2016.

Postponement of Due Date for Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended ("the Act"), requires the Department to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which the Department initiated the investigation. However, if the Department concludes that the parties concerned are cooperating, and that the case is extraordinarily complicated such that additional time is necessary to make the preliminary determination, section 703(c)(l)(B) of the Act allows the Department to postpone making the preliminary determination until no later than 130 days after the date on which the administering authority initiated the investigation. We have concluded that the parties concerned are cooperating and that the case is extraordinarily complicated, such that we will need more time to make the preliminary determination. Specifically, the Department finds that the instant case is extraordinarily complicated by reason of the number and complexity of the alleged countervailable subsidy practices, and the need to determine the extent to which particular alleged countervailable subsidies are used by individual manufacturers, producers and exporters.

Additionally, the Department notes that we issued questionnaires to the respondents in this case on March 1, 2016. The due date for these questionnaires is April 7, 2016, which is only six days before the unextended preliminary determination date. For these reasons we are fully extending the due date until 130 days after the Department's initiation for the preliminary determination. Therefore, the deadline for the completion of the preliminary determination is now June 17, 2016.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).[1]

Dated: March 31, 2016.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2016–07901 Filed 4–5–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will meet on Tuesday, May 3, 2016 from 9:00 a.m. to 5:00 p.m. Eastern Time. The primary purpose of this meeting is to update the Committee on the progress of the implementation of the National Institute of Standards and Technology (NIST) Joplin tornado investigation report's recommendations and receive NIST's response to the Committee's 2015 annual report and recommendations. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST Web site at *http://www.nist.gov/el/disasterstudies/ncst/*.

DATES: The NCST Advisory Committee will meet on Tuesday, May 3, 2016 from 9:00 a.m. until 5:00 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: The meeting will be held in Building 101 Room C121, NIST, 100 Bureau Drive, Gaithersburg, Maryland 20899. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Benjamin Davis, Management and Program Analyst, Community Resilience Program, Engineering Laboratory, NIST, 100 Bureau Drive, Mail Stop 8615, Gaithersburg, Maryland 20899–8604. Mr. Davis' email address is *Benjamin.Davis@nist.gov* and his phone number is (301) 975–6071.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to Section 11 of the NCST Act (Pub. L. 107–231), codified at 15 U.S.C. 7301 *et seq.* The Committee is currently composed of six members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at *http://www.nist.gov/el/disasterstudies/ncst/*.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the NCST Advisory Committee will meet on Tuesday, May 3, 2016, from 9:00 a.m. until 5:00 p.m. Eastern Time. The meeting will be open to the public. The meeting will be held in Building 101 Room C121, NIST, 100 Bureau Drive, Gaithersburg, Maryland 20899. The primary purpose of this meeting is to update the Committee on the progress of the implementation of the NIST Joplin tornado investigation report's recommendations, available at *http://www.nist.gov/el/disasterstudies/upload/Recommendations_Joplin.pdf*, and receive NIST's response to the Committee's 2015 annual report recommendations. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST Web site at *http://www.nist.gov/el/disasterstudies/ncst/*.

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. On May 3, 2016, approximately fifteen minutes will be reserved near the conclusion of the meeting for public comments, and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received, but is likely to be three minutes each. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Mr. Benjamin Davis, *Benjamin.Davis@nist.gov*, by 5:00 p.m. Eastern Time, Tuesday, April 26, 2016. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements to the NCST, National Institute of Standards and Technology, 100 Bureau Drive, MS 8604, Gaithersburg, Maryland 20899–8604, or electronically by email to *Benjamin.Davis@nist.govmailto:*.

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by 5:00 p.m. Eastern Time, Tuesday, April 26, 2016, in order to attend. Please submit your full name, email address, and phone number to Melissa Banner. Non-U.S. citizens must submit additional information; please contact Ms. Banner. Ms. Banner's email address is *Melissa.Banner@nist.gov*, and her phone number is (301) 975–8912. For participants attending in person, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (P.L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Ms. Banner or visit: *http://www.nist.gov/public_affairs/visitor/*.

Phillip A. Singerman,

Associate Director for Innovations and Industry Services.

[FR Doc. 2016–07902 Filed 4–5–16; 8:45 am]

BILLING CODE 3510–13–P

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[1] We acknowledge that the Department inadvertently did not notify the parties to this investigation of this postponement within the timeframe provided in section 703(c)(2) of the Act.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE535

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; new five-year affirmative findings for Ecuador, Guatemala, Mexico, and Spain.

SUMMARY: The NMFS Assistant Administrator (Assistant Administrator) has issued new five-year affirmative findings for the Governments of Ecuador, Guatemala, Mexico, and Spain (Hereafter known as "The Nations") under the Marine Mammal Protection Act (MMPA). These new five-year affirmative findings will allow yellowfin tuna and yellowfin tuna products harvested in the eastern tropical Pacific Ocean (ETP) in compliance with the International Dolphin Conservation Program (IDCP) by The Nations' flagged purse seine vessels or purse seine vessels operating under The Nations' jurisdiction to be imported into the United States. The new five-year affirmative findings were based on reviews of documentary evidence submitted by the Governments of The Nations and obtained from the Inter-American Tropical Tuna Commission (IATTC).

DATES: These new five-year affirmative findings are effective for the five-year period of April 1, 2015, through March 31, 2020.

FOR FURTHER INFORMATION CONTACT: Justin Greenman, West Coast Region, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802. Phone: 562–980–3264. Email: *justin.greenman@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MMPA, 16 U.S.C. 1361 *et seq.,* allows for importation into the United States of yellowfin tuna harvested by purse seine vessels in the ETP under certain conditions. If requested by the harvesting nation, the Assistant Administrator will determine whether to make an affirmative finding based upon documentary evidence provided by the government of the harvesting nation, the IATTC, or the Department of State.

The affirmative finding process requires that the harvesting nation is meeting its obligations under the IDCP and obligations of membership in the IATTC. Every five years, the government of the harvesting nation must request a new affirmative finding and submit the required documentary evidence directly to the Assistant Administrator. On an annual basis, NMFS reviews the affirmative finding and determines whether the harvesting nation continues to meet the requirements. A nation may provide information related to compliance with IDCP and IATTC measures directly to NMFS on an annual basis or may authorize the IATTC to release the information to NMFS to annually renew an affirmative finding determination without an application from the harvesting nation.

An affirmative finding will be terminated, in consultation with the Secretary of State, if the Assistant Administrator determines that the requirements of 50 CFR 216.24(f) are no longer being met or that a nation is consistently failing to take enforcement actions on violations, thereby diminishing the effectiveness of the IDCP.

As a part of the affirmative finding process set forth in 50 CFR 216.24(f), the Assistant Administrator considered documentary evidence submitted by the Governments of The Nations and obtained from the IATTC and has determined that The Nations have met the MMPA's requirements to receive new five-year affirmative findings.

After consultation with the Department of State, the Assistant Administrator issued new five-year affirmative findings to The Nations, allowing the continued importation into the United States of yellowfin tuna and products derived from yellowfin tuna harvested in the ETP by The Nations' flagged purse seine vessels or purse seine vessels operating under The Nations jurisdiction for the five-year period of April 1, 2015, through March 31, 2020.

Dated: March 31, 2016.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–07823 Filed 4–5–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 160331306–6306–01]

RIN 0660–XC024

The Benefits, Challenges, and Potential Roles for the Government in Fostering the Advancement of the Internet of Things

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice, request for public comment.

SUMMARY: Recognizing the vital importance of the Internet to U.S. innovation, prosperity, education, and civic and cultural life, the Department of Commerce has made it a top priority to encourage growth of the digital economy and ensure that the Internet remains an open platform for innovation. Thus, as part of the Department's Digital Economy Agenda, the National Telecommunications and Information Administration (NTIA) is initiating an inquiry regarding the Internet of Things (IoT) to review the current technological and policy landscape. Through this Notice, NTIA seeks broad input from all interested stakeholders—including the private industry, researchers, academia, and civil society—on the potential benefits and challenges of these technologies and what role, if any, the U.S. Government should play in this area. After analyzing the comments, the Department intends to issue a "green paper" that identifies key issues impacting deployment of these technologies, highlights potential benefits and challenges, and identifies possible roles for the federal government in fostering the advancement of IoT technologies in partnership with the private sector.

DATES: Comments are due on or before 5 p.m. Eastern Time on May 23, 2016.

ADDRESSES: Written comments may be submitted by email to *iotrfc2016@ntia.doc.gov.* Comments submitted by email should be machine-readable and should not be copy-protected. Written comments also may be submitted by mail to the National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Attn: IOT RFC 2016, Washington, DC 20230. Responders should include the name of the person or organization filing the comment, as well as a page number on each page of their submissions. All comments received are a part of the public record and will generally be posted to *http://www.ntia.doc.gov/category/internet-policy-task-force* without change. All personal identifying information (for example, name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NTIA will accept anonymous comments.

FOR FURTHER INFORMATION CONTACT: Travis Hall, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Room 4725, Washington, DC 20230; telephone (202) 482–3522; email *thall@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002.

SUPPLEMENTARY INFORMATION:

Background: As part of the Department of Commerce's Digital Economy Agenda, the National Telecommunications and Information Administration (NTIA) is requesting comment on the benefits, challenges, and potential roles for the government in fostering the advancement of the Internet of Things (IoT).

Description of IoT and its Impact on the Economy: IoT is the broad umbrella term that seeks to describe the connection of physical objects, infrastructure, and environments to various identifiers, sensors, networks, and/or computing capability.[1] In practice, it also encompasses the applications and analytic capabilities driven by getting data from, and sending instructions to, newly-digitized devices and components.

Although a number of architectures describing different aspects or various applications of the IoT are being developed, there is no broad consensus on exactly how the concept should be defined or scoped. Consensus has emerged, however, that the number of connected devices is expected to grow exponentially, and the economic impact of those devices will increase dramatically.[2] While some types of devices will fall into readily identifiable commercial or public sectors in their own right—for example, implantable health devices—most will serve the function of enabling existing industries to better track, manage, and automate their core functions. The potential health, safety, environmental, commercial, and other benefits of IoT are enormous, from reducing the risk of automobile-related injuries and fatalities to enabling micro-cell weather forecasting. IoT has the potential to catalyze new user applications and give rise to new industries. For example, IoT is the foundation for "Smart Cities" efforts, which use pervasive connectivity and data-driven technologies to better manage resources, meet local challenges, and improve quality of life.

However, the IoT also presents challenges,[3] which in turn have begun to generate initial thinking and policy responses both inside and outside of government. A number of Federal agencies—for example, the National Highway Traffic Safety Administration (NHTSA) and the Food and Drug Administration (FDA)—have already begun grappling with potential health, safety, and security issues arising from the connection of cars and medical devices to the Internet.[4] The Federal Trade Commission (FTC) has identified privacy and cybersecurity aspects of IoT, and proposed some possible best practices.[5] Pursuant to the White House Smart Cities Initiative, the U.S. Government is providing $35 million in new grants and nearly $70 million in new spending on Smart Cities across several departments.[6] Additional activities at the federal level seek to take advantage of the potential opportunities as well as address any possible issues raised by the deployment of IoT in relation to agency missions. IoT has also garnered interest by other national governments, standards organizations, and intergovernmental organizations that are interested in understanding how to engage in the IoT ecosystem to encourage economic growth and innovation.[7] Unfortunately, country specific strategies threaten the possibility of a global patchwork of approaches to IoT, which would increase costs and delay the launch of new products and services, dampening investment. The U.S. government will need to work with stakeholders to develop industry-driven solutions; however, thus far no U.S. government agency is taking a holistic, ecosystem-wide view that identifies opportunities and assesses risks across the digital economy.

The Department's Digital Economy Initiatives: More than six years ago, the Department created the Internet Policy Task Force (IPTF) to identify and address leading public policy and operational challenges in the Internet ecosystem. The IPTF collaborates across bureaus at the Department, seeks public comment, and has produced policy papers on a variety of important topics.

In recognition of the broad impact that the Internet and digitization are having across the economy, in 2015 the Department created the Digital Economy Leadership Team (DELT). Comprised of senior officials from across the Department, the DELT provides high-level guidance and coordination, leveraging the substantial expertise within the agency to promote initiatives that have a positive impact on the digital economy and society. The DELT currently focuses on the four pillars of the Department's 2015–16 Digital Economy Agenda: promoting a free and open Internet worldwide; promoting trust and confidence online; ensuring

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[1] The term was initially coined by Kevin Ashton in 1999 in a presentation at Proctor and Gamble in reference to radio-frequency identification tags (RFIDs). *See* Kevin Ashton, *That 'Internet of Things' Thing,* RFID Journal (June 22, 2009), *http://www.rfidjournal.com/articles/view?4986.*

[2] In 2003, there were only around 500 million connected devices, but by 2015 there were around 25 billion connected devices. Devices now outnumber people by 3.5 to 1. (Intel, *A Guide to the Internet of Things Infographic,* available at *http://www.intel.com/content/www/us/en/internet-of-things/infographics/guide-to-iot.html*). It is expected by 2020 that there will be up to 200 billion connected devices and these devices will outnumber people by 26 to 1. The McKinsey Global Institute estimates that the cross-sector impact of IoT technologies will be between $3.9 trillion and $11 trillion by 2025. *See* James Manyika et al, *Unlocking the Potential of the Internet of Things,* McKinsey & Co. (June 2015), *http://www.mckinsey.com/insights/business_technology/the_internet_of_things_the_value_of_digitizing_the_physical_world.*

[3] See, for example, the concerns laid out by the National Security Telecommunications Advisory Committee (NSTAC) in *NSTAC Report to the President on the Internet of Things* (Nov. 2014), pg. 21–22. *https://www.dhs.gov/sites/default/files/publications/NSTAC%20Report%20to%20the%20President%20on%20the%20Internet%20of%20Things%20Nov%202014%20%28updat%20%20%20.pdf.*

[4] *See* U.S. Dept. of Health and Human Services, *Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (Aug. 14, 2013), *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf;* see also NHTSA, *Vehicle-to-Vehicle Communications* (last accessed March 9, 2016), *http://www.safercar.gov/v2v/index.html.*

[5] Federal Trade Comm'n, *FTC Report on Internet of Things Urges Companies to Adopt Best Practices to Address Consumer Privacy and Security Risks,* FTC (Jan. 27, 2015), *https://www.ftc.gov/news-events/press-releases/2015/01/ftc-report-internet-things-urges-companies-adopt-best-practices.*

[6] The White House, *FACT SHEET: Administration Announces New "Smart Cities" Initiative to Help communities Tackle Local Challenges and Improve City Services,* The White House Office of the Press Secretary (Sept. 14, 2015), *https://www.whitehouse.gov/the-press-office/2015/09/14/fact-sheet-administration-announces-new-smart-cities-initiative-help.*

[7] For example, the Internet Engineering Task Force (IETF), International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and ISO and IEC's Joint Technical Committee 1 (ISO/IEC JTC1) and the International Telecommunications Union's Standardization Sector (ITU–T) have initiated discussion and work related to IoT.

Internet access for workers, families, and companies; and promoting innovation in the digital economy. Working closely together, the DELT and IPTF ensure that the Department is helping businesses and consumers realize the potential of the digital economy to advance growth and opportunity.

Given the cross-cutting nature of the IoT landscape, the Department of Commerce—through the DELT and IPTF—is able to provide important perspective and expertise on IoT. The mission of the Department is to help establish conditions that will enable the private sector to grow the economy, innovate, and create jobs. The Department also has statutory authority, expertise, and ongoing work streams in numerous areas that are critical to the development of IoT, including: cybersecurity, privacy, cross-border data flows, spectrum, international trade, advanced manufacturing, protection of intellectual property, standards policy, Internet governance, big data, entrepreneurship, and worker skills. For example:

- The Department has long standing technological and policy expertise and experience that it is applying to IoT. The Department's National Institute of Standards and Technology (NIST) has coordinated the development of a draft reference architecture for Cyber-Physical Systems and is conducting a Global City Teams Challenge to foster the development of Smart Cities and promote interoperability. NTIA's spectrum planning and management activities contemplate the growth of IoT and its Institute for Telecommunications Sciences (ITS) has begun testing the possible effects of IoT on spectrum usage. Both NIST and NTIA have been actively engaged with international standards bodies and international organizations on aspects of IoT and other related areas (*e.g.,* cybersecurity), and have been further engaged with other Federal agencies.
- The Economic Development Administration (EDA) provides grants to communities around the country to build up their technology-focused innovation ecosystems in order to grow their local economies and create jobs.
- The U.S. Patent and Trademark Office (USPTO) continues to improve its patent quality, especially in new technological domains, including IoT. USPTO also plays a key role in the alignment of intellectual property policies around the world, so that U.S. inventors of IoT technology can have access to the protections they need to continue innovating and sell their products and services everywhere.
- The International Trade Administration (ITA) is an active promoter of IoT and Smart Cities on the international stage, including participation in the CS Europe Smart Cities Initiative and working with the other Federal agencies to consider innovative financing mechanisms for Smart City projects. ITA hosts roundtables on an ad hoc basis with the private sector and federal partners to discuss Smart Cities and infrastructure financing. In addition, ITA's Office of Textiles and Apparel is holding a Smart Fabrics Summit (*http://smartfabricssummit.com/*) on April 11, 2016.

The Department, through this RFC and subsequent green paper, will capitalize on the Department's experience and holistic economic perspective to craft an approach to IoT and its potential impacts that will best foster IoT innovation and growth. Where relevant, comments received may also inform the work of other federal initiatives, such as the recently created Commission on Enhancing National Cybersecurity.

Request for Comment:

Instructions for Commenters: The Department invites comment on the full range of issues that may be presented by this inquiry, including issues that are not specifically raised in the following questions. Commenters are encouraged to address any or all of the following questions. To the extent commenters choose to respond to the specific questions asked, responses should generally follow the below structure and note the number corresponding to the question. Comments that contain references to studies, research, and other empirical data that are not widely published should include copies of the referenced materials with the submitted comments.

For any response, commenters may wish to consider describing specific goals or actions that the Department of Commerce, or the U.S. Government in general, might take (on its own or in conjunction with the private sector) to achieve those goals; the benefits and costs associated with the action; whether the proposal is agency-specific or interagency; the rationale and evidence to support it; and the roles of other stakeholders.

General:

1. Are the challenges and opportunities arising from IoT similar to those that governments and societies have previously addressed with existing technologies, or are they different, and if so, how?

a. What are the novel technological challenges presented by IoT relative to existing technological infrastructure and devices, if any? What makes them novel?

b. What are the novel policy challenges presented by IoT relative to existing technology policy issues, if any? Why are they novel? Can existing policies and policy approaches address these new challenges, and if not, why?

c. What are the most significant new opportunities and/or benefits created by IoT, be they technological, policy, or economic?

2. The term "Internet of Things" and related concepts have been defined by multiple organizations, including parts of the U.S. Government such as NIST and the FTC, through policy briefs and reference architectures.[8] What definition(s) should we use in examining the IoT landscape and why? What is at stake in the differences between definitions of IoT? What are the strengths and limitations, if any, associated with these definitions?

3. With respect to current or planned laws, regulations, and/or policies that apply to IoT:

a. Are there examples that, in your view, foster IoT development and deployment, while also providing an appropriate level of protection to workers, consumers, patients, and/or other users of IoT technologies?

b. Are there examples that, in your view, unnecessarily inhibit IoT development and deployment?

4. Are there ways to divide or classify the IoT landscape to improve the precision with which public policy issues are discussed? If so, what are they, and what are the benefits or limitations of using such classifications? Examples of possible classifications of IoT could include: Consumer vs. industrial; public vs. private; device-to-device vs. human interfacing.

5. Please provide information on any current (or concluded) initiatives or research of significance that have examined or made important strides in understanding the IoT policy landscape. Why do you find this work to be significant?

Technology: Technology is at the heart of IoT and its applications. IoT development is being driven by a very diverse set of stakeholders whose expertise in science, research, development, deployment, measurements and standards are enabling rapid advances in technologies for IoT. It is important to understand what technological hurdles still exist, or may arise, in the development and deployment of IoT, and if the government can play a role in mitigating these hurdles.

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[8] Federal Trade Comm'n, *Internet of Things: Privacy and Security in a Connected World,* FTC (Jan. 2015), *https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf;* Abdella Battou, *CPS PWG: Reference Architecture,* National Institute of Standards and Technology (accessed March 9, 2016), *http://www.nist.gov/cps/cpspwg_refarch.cfm.*

6. What technological issues may hinder the development of IoT, if any?

a. Examples of possible technical issues could include:

i. Interoperability
ii. Insufficient/contradictory/proprietary standards/platforms
iii. Spectrum availability and potential congestion/interference
iv. Availability of network infrastructure
v. Other

b. What can the government do, if anything, to help mitigate these technical issues? Where may government/private sector partnership be beneficial?

7. NIST and NTIA are actively working to develop and understand many of the technical underpinnings for IoT technologies and their applications. What factors should the Department of Commerce and, more generally, the federal government consider when prioritizing their technical activities with regard to IoT and its applications, and why?

Infrastructure: Infrastructure investment, innovation, and resiliency (such as across the information technology, communications, and energy sectors) will provide a foundation for the rapid growth of IoT services.

8. How will IoT place demands on existing infrastructure architectures, business models, or stability?

9. Are there ways to prepare for or minimize IoT disruptions in these infrastructures? How are these infrastructures planning and evolving to meet the demands of IoT?

10. What role might the government play in bolstering and protecting the availability and resiliency of these infrastructures to support IoT?

Economy: IoT has already begun to alter the U.S. economy by enabling the development of innovative consumer products and entirely new economic sectors, enhancing a variety of existing products and services, and facilitating new manufacturing and delivery systems. In light of this, how should we think of and assess IoT and its effects? The questions below are an effort to understand both the potential economic implications of IoT for the U.S. economy, as well as how to quantify and analyze the economic impact of IoT in the future. The Department is interested in both the likely implications of IoT on the U.S. economy and society, as well as the tools that could be used to quantify that impact.

11. Should the government quantify and measure the IoT sector? If so, how?

a. As devices manufactured or sold (in value or volume)?

b. As industrial/manufacturing components?

c. As part of the digital economy?

i. In providing services
ii. In the commerce of digital goods

d. In enabling more advanced manufacturing and supply chains?

e. What other metrics would be useful, if any? What new data collection tools might be necessary, if any?

f. How might IoT fit within the existing industry classification systems? What new sector codes are necessary, if any?

12. Should the government measure the economic impact of IoT? If so, how?

a. Are there novel analytical tools that should be applied?

b. Does IoT create unique challenges for impact measurement?

13. What impact will the proliferation of IoT have on industrial practices, for example, advanced manufacturing, supply chains, or agriculture?

a. What will be the benefits, if any?

b. What will be the challenges, if any?

c. What role or actions should the Department of Commerce and, more generally, the federal government take in response to these challenges, if any?

14. What impact (positive or negative) might the growth of IoT have on the U.S. workforce? What are the potential benefits of IoT for employees and/or employers? What role or actions should the government take in response to workforce challenges raised by IoT, if any?

Policy Issues: A growing dependence on embedded devices in all aspects of life raises questions about the confidentiality of personal data, the integrity of operations, and the availability and resiliency of critical services.

15. What are the main policy issues that affect or are affected by IoT? How should the government address or respond to these issues?

16. How should the government address or respond to cybersecurity concerns about IoT?

a. What are the cybersecurity concerns raised specifically by IoT? How are they different from other cybersecurity concerns?

b. How do these concerns change based on the categorization of IoT applications (*e.g.,* based on categories for Question 4, or consumer vs. industrial)?

c. What role or actions should the Department of Commerce and, more generally, the federal government take regarding policies, rules, and/or standards with regards to IoT cybersecurity, if any?

17. How should the government address or respond to privacy concerns about IoT?

a. What are the privacy concerns raised specifically by IoT? How are they different from other privacy concerns?

b. Do these concerns change based on the categorization of IoT applications (*e.g.,* based on categories for Question 4, or consumer vs. industrial)?

c. What role or actions should the Department of Commerce and, more generally, the federal government take regarding policies, rules, and/or standards with regards to privacy and the IoT?

18. Are there other consumer protection issues that are raised specifically by IoT? If so, what are they and how should the government respond to the concerns?

19. In what ways could IoT affect and be affected by questions of economic equity?

a. In what ways could IoT potentially help disadvantaged communities or groups? Rural communities?

b. In what ways might IoT create obstacles for these communities or groups?

c. What effects, if any, will Internet access have on IoT, and what effects, if any, will IoT have on Internet access?

d. What role, if any, should the government play in ensuring that the positive impacts of IoT reach all Americans and keep the negatives from disproportionately impacting disadvantaged communities or groups?

International Engagement: As mentioned earlier, efforts have begun in foreign jurisdictions, standards organizations, and intergovernmental bodies to explore the potential of, and develop standards, specifications, and best practices for IoT. The Department is seeking input on how to best monitor and/or engage in various international fora as part of the government's ongoing efforts to encourage innovation and growth of the digital economy.

20. What factors should the Department consider in its international engagement in:

a. Standards and specification organizations?

b. Bilateral and multilateral engagement?

c. Industry alliances?

d. Other?

21. What issues, if any, regarding IoT should the Department focus on through international engagement?

22. Are there Internet governance issues now or in the foreseeable future specific to IoT?

23. Are there policies that the government should seek to promote with international partners that would be helpful in the IoT context?

24. What factors can impede the growth of the IoT outside the U. S. (*e.g.,* data or service localization requirements or other barriers to trade), or otherwise constrain the ability of U.S. companies to provide those services on a global basis? How can the government help to alleviate these factors?

Additional Issues:

25. Are there IoT policy areas that could be appropriate for multistakeholder engagement, similar to the NTIA-run processes on privacy and cybersecurity?

26. What role should the Department of Commerce play within the federal government in helping to address the challenges and opportunities of IoT? How can the Department of Commerce best collaborate with stakeholders on IoT matters?

27. How should government and the private sector collaborate to ensure that infrastructure, policy, technology, and investment are working together to best fuel IoT growth and development? Would an overarching strategy, such as those deployed in other countries, be useful in this space? If the answer is yes, what should that strategy entail?

28. What are any additional relevant issues not raised above, and what role, if any, should the Department of Commerce and, more generally, the federal government play in addressing them?

Dated: April 1, 2016.

Lawrence E. Strickling,

Assistant Secretary for Communications and Information.

[FR Doc. 2016–07892 Filed 4–5–16; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2016–HQ–0011]

Privacy Act of 1974; System of Records

AGENCY: Department of the Army, DoD.

ACTION: Notice to alter a system of records.

SUMMARY: The Department of the Army proposes to alter a system of records, A0600–37b DAPE, entitled "Unfavorable Information Files," to record Board action and to provide pattern of subsequent unfavorable information. Information filed in the performance portion of the Official Military Personnel File is also used by Department of Army promotion/selection boards when the individual has been afforded due process.

DATES: Comments will be accepted on or before May 6, 2016. This proposed action will be effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov* Follow the instructions for submitting comments.

* *Mail:* ODCMO, Directorate for Oversight and Compliance, 4800 Mark Center Drive, ATTN: Mailbox 24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Tracy Rogers, Department of the Army, Privacy Office, U.S. Army Records Management and Declassification Agency, 7701 Telegraph Road, Casey Building, Suite 144, Alexandria, VA 22325–3905 or by calling (703) 428–6185.

SUPPLEMENTARY INFORMATION: The Department of the Army's notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or from the Defense Privacy and Civil Liberties Division Web site at *http://dpcld.defense.gov/.*

The proposed systems reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, as amended, were submitted on March 28, 2016, to the House Committee on Oversight and Government Reform, the Senate Committee on Homeland Security and Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: April 1, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0600–37b DAPE

SYSTEM NAME:

Unfavorable Information Files (December 8, 2000, 65 FR 77002)

CHANGES:

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CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with "Summary of unfavorable information, copy of letter of notification to individual, individual's response or appeal, summary of consideration of response or appeal, disposition determination, and voting record of Board members. Personal data includes full name, Social Security Number (SSN), DoD ID number, grade/rank, mailing address, email, unit and location at discharge or separation, work and home telephone numbers."

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with "10 U.S.C. 3013, Secretary of the Army; Department of Defense Directive 1030.01, Victim and Witness Assistance; DoDI 1030.2, Victim and Witness Assistance Procedures; and Army Regulation 600–37, Unfavorable Information; and E.O. 9397 (SSN), as amended."

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with "In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To victims and witnesses of a crime for purposes of providing information, consistent with the requirements of the Victim and Witness Assistance Program, regarding the investigation and disposition of an offense.

The DoD Blanket Routine Uses set forth at the beginning of the Army's compilation of systems of records notices may apply to this system. The complete list of DoD Blanket Routine Uses can be found online at: *http://dpcld.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx.*"

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

STORAGE:

Delete entry and replace with "Paper records and electronic storage media."

RETRIEVABILITY:

Delete entry and replace with "By individual's full name and SSN/DoD ID Number."

SAFEGUARDS:

Delete entry and replace with "Paper records in file cabinets are accessible only to authorized personnel who are properly instructed in the permissible use. The files are not accessible to the public or to persons within the command without an official need to know. File cabinets have locking capabilities and offices are locked during non-work hours. Army Activities and approved users ensure that electronic records collected and used are maintained in controlled areas accessible only to authorized personnel. Access to computerized data is restricted by use of Common Access Cards (CACs) and is accessible only by users with an authorized account. The system and electronic backups are maintained in controlled facilities that employ physical restrictions and safeguards such as security guards, identification badges, key cards, and locks."

* * * * *

NOTIFICATION PROCEDURE:

Delete entry and replace with "Individuals seeking to determine if information about themselves is contained in this system should address written inquiries to the Deputy Chief of Staff for Personnel, Department of the Army, 4000 Army Pentagon, Washington, DC 20310–4000.

Inquirer should furnish full name, SSN/DoD ID Number, current address and telephone number, and sufficient details concerning time and place of event to ensure locating pertinent records, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

IF EXECUTED OUTSIDE THE UNITED STATES:

'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'."

RECORD ACCESS PROCEDURES:

Delete entry and replace with "Individuals seeking access to information about themselves contained in this system should address written request to the Deputy Chief of Staff for Personnel, Headquarters, Department of the Army, ATTN: DAPE–MPD, 4000 Army Pentagon, Washington, DC 20310–4000.

Inquirer should furnish full name, SSN/DoD ID Number, current address and telephone number, and sufficient details concerning time and place of event to ensure locating pertinent records, and signature.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

IF EXECUTED OUTSIDE THE UNITED STATES:

'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'."

CONTESTING RECORD PROCEDURES:

Delete entry and replace with "The Army's rules for accessing records, and for contesting contents and appealing initial agency determinations are contained in 32 CFR part 505, Army Privacy Program; or may be obtained from the system manager."

* * * * *

[FR Doc. 2016–07879 Filed 4–5–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2016–OS–0033]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Policy, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Office of the Under Secretary of Defense for Policy announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by June 6, 2016.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* ODCMO, Directorate for Oversight and Compliance, 4800 Mark Center Drive, ATTN: Mailbox 24, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Leadership and Organizational Development Office, 2400 Defense Pentagon, Room 5B683, ATTN: Dr. James Cully, Washington, DC 20301–2400, or call, at 703.695.7386.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: OUSD—Policy Pulse Survey 2016; OMB Control Number 0704–XXXX.

Needs and Uses: The information collection requirement is necessary to obtain and record responses from contractor personnel employed within the Office of the Under Secretary of Defense for Policy and its components. The survey results are analyzed by the Leadership and Organizational Development Office to assess the progress of the current human capital strategy and to address emerging human capital and training issues.

Affected Public: Business.

Annual Burden Hours: 76.5.

Number of Respondents: 153.

Responses Per Respondent: 2.

Annual Responses: 306.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Respondents are defense contractors employed by Office of the Under Secretary of Defense for Policy who provide analytic, administrative, and operations services. The survey is administered to all employees of the Office of Secretary of Defense for Policy as required by the Under Secretary of Defense for Policy to assess the effectiveness and progress of the current human capital strategy. If contractors are not permitted to take the survey then the assessment effectively excludes ~20% of the employee population, diminishing the accuracy of the survey and resulting conclusions.

Dated: April 1, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–07848 Filed 4–5–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0041]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Teacher Incentive Fund (TIF) Application (1894–0001)

AGENCY: Office of Innovation and Improvement (OII), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before May 6, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0041. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–115, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Corinne Sauri, 202–260–2533.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Teacher Incentive Fund (TIF) Application (1894–0001).

OMB Control Number: 1855-New.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 120.

Total Estimated Number of Annual Burden Hours: 29,760.

Abstract: The Teacher Incentive Fund (TIF) is a competitive grant program through the Department of Education, Office of Innovation and Improvement. The TIF is designed to support projects that develop and implement performance-based compensation systems for teachers, principals, and other personnel in order to increase educator effectiveness and student achievement in high-need schools.

Dated: April 1, 2016.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–07849 Filed 4–5–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Certification Notice—238]

Notice of Filing of Self-Certification of Coal Capability Under the Powerplant and Industrial Fuel Use Act

AGENCY: Office of Electricity Delivery and Energy Reliability, DOE.

ACTION: Notice of Filing.

SUMMARY: On March 15, 2016, Middlesex Energy Center, LLC, as owner and operator of a new combined cycle electric powerplant, submitted a coal capability self-certification to the Department of Energy (DOE) pursuant to § 201(d) of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended, and DOE regulations in 10 CFR 501.60, 61. FUA and regulations thereunder require DOE to publish a notice of filing of self-certification in the **Federal Register**. 42 U.S.C. 8311(d) and 10 CFR 501.61(c).

ADDRESSES: Copies of coal capability self-certification filings are available for public inspection, upon request, in the Office of Electricity Delivery and Energy Reliability, Mail Code OE–20, Room 8G–024, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Christopher Lawrence at (202) 586–5260.

SUPPLEMENTARY INFORMATION: Title II of FUA, as amended (42 U.S.C. 8301 *et seq.*), provides that no new base load electric powerplant may be constructed or operated without the capability to use coal or another alternate fuel as a primary energy source. Pursuant to FUA in order to meet the requirement of coal capability, the owner or operator of such a facility proposing to use natural gas or petroleum as its primary energy source shall certify to the Secretary of Energy (Secretary) prior to construction, or prior to operation as a base load electric powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with FUA section 201(a) as of the date it is filed with the Secretary. 42 U.S.C. 8311.

The following owner of a proposed new combined cycle electric powerplant has filed a self-certification of coal-capability with DOE pursuant to FUA section 201(d) and in accordance with DOE regulations in 10 CFR 501.60, 61:

OWNER: Middlesex Energy Center, LLC,

CAPACITY: 560 megawatts (MW).

PLANT LOCATION: Borough of Sayreville, Middlesex County, New Jersey.

IN-SERVICE DATE: May 2019.

Issued in Washington, DC, on March 30, 2016.

Christopher Lawrence,

Electricity Policy Analyst, Office of Electricity Delivery and Energy Reliability.

[FR Doc. 2016–07874 Filed 4–5–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Notice of the Stakeholder Meeting To Receive Input on the U.S. Department of Energy (DOE) Outyear Marine and Hydrokinetic Program Strategy

AGENCY: Wind and Water Power Technologies Office, Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Notice of the Stakeholder Meeting.

SUMMARY: The Wind and Water Power Technologies Office within the U.S. DOE intends to hold a Stakeholder Meeting on the request for information (RFI) to receive input for the U.S. DOE Outyear Marine and Hydrokinetic Program Strategy in Washington, DC on April 27, 2016. The RFI is posted on the EERE Exchange Web site: *https://goo.gl/Ei6ppc*. Due to space constraints, there is limited seating, therefore the public meeting will be open to a limited number of parties. If you are interested in attending the meeting, please express interest in attending by emailing *MHKRFI1570@ee.doe.gov*. Please include with the subject line "Meeting Interest," your name, organization, and contact information. The deadline to send notice of your interest, or interested parties, is Friday, April 8 at 11:59 p.m. ET. You will be notified via email on April 11 if you were confirmed as an attendee. All individuals, including those not able to attend will have the opportunity to submit comments to the RFI until 5:00 p.m. ET April 29, 2016.

DATES: DOE will host the Stakeholder Meeting from 12:00 p.m. to 5:00 p.m. on Wednesday, April 27, 2016.

ADDRESSES: The meeting will be held at the Capitol Hilton, 1001 16th St. NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Maggie Yancey, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585. Telephone: (202) 586–4536. For email, please include in the subject line "Further Information," and in the body of the email: your name, organization, contact information, and your specific question or inquiry. *MHKRFI1570@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

Public Participation

The event is open to the public based upon space availability. All individuals, including those not able to attend will have the opportunity to submit comments to the RFI until 5:00 p.m. ET April 29, 2016. The RFI is posted on the EERE Exchange Web site: *https://goo.gl/Ei6ppc*. Participants should limit information and comments to those based on personal experience, individual advice, information, or facts regarding this topic. It is not the object of this session to obtain any group position or consensus from the meeting participants. To most effectively use the limited time, please refrain from passing judgment on another participant's recommendations or advice, and instead, concentrate on your individual experiences.

Issued on April 1, 2016 in Washington, DC.

Mark Higgins,

Deputy Director, Wind and Water Power Technologies Office, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 2016–07867 Filed 4–5–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC16–96–000.
Applicants: Tucson Electric Power Company.
Description: Application of Tucson Electric Power Company under FPA Section 203.
Filed Date: 3/29/16.
Accession Number: 20160329–5214.
Comments Due: 5 p.m. ET 5/31/16.

Docket Numbers: EC16–97–000.
Applicants: GP Renewables & Trading, LLC.
Description: Application of GP Renewables & Trading LLC for Approval Pursuant to Section 203 of the Federal Power Act.
Filed Date: 3/30/16.
Accession Number: 20160330–5279.
Comments Due: 5 p.m. ET 4/20/16.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–77–000.
Applicants: MS Solar 3, LLC.
Description: Self-Certification of EG or FC of MS Solar 3, LLC.
Filed Date: 3/31/16.
Accession Number: 20160331–5039.
Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: EG16–78–000.
Applicants: MS Solar 2, LLC.
Description: Self-Certification of EG or FC of MS Solar 2, LLC.
Filed Date: 3/31/16.
Accession Number: 20160331–5040.
Comments Due: 5 p.m. ET 4/21/16.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1939–003.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: Order 1000 Interregional Compliance Filing Pursuant to the February 2 Order to be effective 1/1/2015.
Filed Date: 3/3/16.
Accession Number: 20160303–5149.
Comments Due: 5 p.m. ET 4/11/16.

Docket Numbers: ER15–2265–002.
Applicants: Southwest Power Pool, Inc.
Description: Compliance filing: Compliance Filing Revising Resource Hubs to be effective 9/23/2015.
Filed Date: 3/30/16.
Accession Number: 20160330–5247.
Comments Due: 5 p.m. ET 4/20/16.

Docket Numbers: ER16–1293–000.
Applicants: White Oak Solar, LLC
Description: Baseline eTariff Filing: White Oak Solar, LLC Application for Market-Based Rates to be effective 5/29/2016.
Filed Date: 3/30/16.
Accession Number: 20160330–5248.
Comments Due: 5 p.m. ET 4/20/16.

Docket Numbers: ER16–1294–000.

Applicants: Southwest Power Pool, Inc.

Description: Notice of Termination of Settlement Agreement No. 494 of Southwest Power Pool, Inc.

Filed Date: 3/30/16.

Accession Number: 20160330–5249.

Comments Due: 5 p.m. ET 4/20/16.

Docket Numbers: ER16–1295–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: § 205(d) Rate Filing: 2016 Member Rate Schedule Tariff Filing to be effective 7/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5013.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1296–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: Revisions to Forward Reserve Heat Rate Calculation to be effective 6/15/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5058.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1297–000.

Applicants: Mississippi Power Company.

Description: § 205(d) Rate Filing: MRA 27 Rate Case Filing to be effective 5/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5096.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1298–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: DSA State of CA. Dept. of Water Resources Citrus Pump Station Project to be effective 4/15/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5108.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1299–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt Painted Hills Wind Developers to be effective 4/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5113.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1300–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt New-Indy Oxnard, LLC to be effective 4/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5122.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1302–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: SCE Amends 4 Agmts—2016 Revised Added Facilities Rate & ISO Rate to be effective 1/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5191.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1303–000.

Applicants: Entergy Louisiana, LLC.

Description: § 205(d) Rate Filing: ELL–SRMPA 9th Extension of Interim Agreement to be effective 4/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5222.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1304–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to MISO–PJM JOA re: MISO Corporate Name Change to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5228.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1305–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: SPP–MISO JOA Revisions to Update MISO's Name and Other Clean-up Edits to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5230.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1306–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: PacifiCorp Energy Construction Agmt ? Pavant 2 to be effective 3/21/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5232.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1307–000.

Applicants: ITC Interconnection LLC, Michigan Electric Transmission Company,, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: ITC & Michigan Electric submit Interconnection Agreement No. 4427 to be effective 6/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5234.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1308–000.

Applicants: Wisconsin Public Service Corporation.

Description: § 205(d) Rate Filing: Common Facilities Agreement between WPSC and ATCLLC to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5244.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1309–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–03–31_MISO–PJM JOA Name Change Filing to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5247.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1310–000.

Applicants: Wisconsin Public Service Corporation.

Description: § 205(d) Rate Filing: Project Services Agreement between WPSC and ATCLLC to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5249.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1311–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–03–31_MISO–SPP JOA Name Change Filing to be effective 5/30/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5255.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1312–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 1771R6 NPPD NITSA NOA to be effective 3/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5260.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1313–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–03–31_Attachment GG Cross-Reference Revisions to be effective 4/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5266.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1314–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 2198R20 Kansas Power Pool NITSA NOA to be effective 3/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5270.

Comments Due: 5 p.m. ET 4/21/16.

Docket Numbers: ER16–1315–000.

Applicants: American Electric Power Service Corporation, ITC Interconnection LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: AEP submits Original Interconnection Agreement No. 4426 with ITCI to be effective 6/1/2016.

Filed Date: 3/31/16.

Accession Number: 20160331–5353.

Comments Due: 5 p.m. ET 4/21/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 31, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–07857 Filed 4–5–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1275–000]

Innovative Solar 46, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Innovative Solar 46, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 20, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 31, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–07855 Filed 4–5–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–52–000]

Michigan South Central Power Agency; Notice of Filing

Take notice that on March 30, 2016, Michigan South Central Power Agency (MSCPA) filed a notice of cancellation of Original Sheet 1 which set forth MSCPA's Reactive Support Revenue Requirement for the provision of Reactive Supply and Voltage Control from Generation Sources Services to the Midcontinent Independent System Operator from the Endicott Generating Station, effective June 1, 2016.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on April 20, 2016.

Dated: March 31, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–07854 Filed 4–5–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–1277–000]

White Pine Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of White Pine Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 20, 2016.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: March 31, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–07856 Filed 4–5–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–117–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Availability of the Environmental Assessment for the Proposed Dalton Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Dalton Expansion Project (Project), proposed by Transcontinental Gas Pipe Line, LLC (Transco) in the above-referenced docket. Transco requests authorization to construct and operate about 113 miles of new natural gas pipeline and associated facilities in Coweta, Carroll, Douglas, Paulding, Bartow, Gordon, and Murray Counties, Georgia and a new compressor station in Carroll County, Georgia. Additionally, Transco plans to modify existing facilities along its mainline transmission system in Virginia and North Carolina to accommodate bidirectional flow. Transco has indicated that the Project would provide 448,000 dekatherms per day of incremental firm transportation service to markets in northwest Georgia.

The EA assesses the potential environmental effects of the construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The proposed Dalton Expansion Project includes the following facilities:

- A new 21,830 horsepower compressor station (Compressor Station 116) in Carroll County, Georgia;
- three new meter stations in Bartow and Murray Counties, Georgia;
- about 7.6 miles of new 30-inch-diameter pipeline in Coweta and Carroll Counties, Georgia;
- 48.2 miles of new 24-inch-diameter pipeline in Carroll, Douglas, Paulding, and Bartow Counties, Georgia;
- 53.5 miles of new 20-inch-diameter pipeline in Bartow, Gordon, and Murray Counties, Georgia;
- 1.5 miles of new 16-inch-diameter pipeline in Murray County, Georgia; and ancillary facilities associated with the new pipeline including mainline valves and pig1 launcher/receiver facilities.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding. In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at:

Federal Energy Regulatory Commission,
Public Reference Room, 888 First
Street NE., Room 2A, Washington, DC
20426, (202) 502–8371

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before May 2, 2016.

For your convenience, there are three methods you can use to file your comments to the Commission. In all instances, please reference the project docket number (CP15–117–000 with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You must select the type of filing you are making. If you are filing a comment on a particular project, please select "Comment on a Filing"; or

(3) You can file a paper copy of your comments by mailing them to the following address:

Kimberly D. Bose, Secretary, Federal
Energy Regulatory Commission, 888
First Street NE., Room 1A,
Washington, DC 20426

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision.

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[1] See the previous discussion on the methods for filing comments.

The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search," and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP15–117). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: March 31, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–07853 Filed 4–5–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9944–69–OA]

Request for Nominations of Candidates to the EPA's Clean Air Scientific Advisory Committee (CASAC) and the EPA Science Advisory Board (SAB)

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) invites nominations of scientific experts from a diverse range of disciplines to be considered for appointment to the Clean Air Scientific Advisory Committee (CASAC) and the EPA Science Advisory Board (SAB) and five SAB committees described in this notice. Appointments are anticipated to be filled by the start of Fiscal Year 2017 (October 2016).

DATES: Nominations should be submitted in time to arrive no later than May 6, 2016.

FOR FURTHER INFORMATION: Nominators unable to submit nominations electronically as described below may submit a paper copy to the Designated Federal Officers (DFO) for the committees, as identified below. General inquiries regarding the work of the CASAC, the SAB or SAB committees also may be directed to the appropriate DFO.

Background: The CASAC is a chartered Federal Advisory Committee, established pursuant to the Clean Air Act (CAA) Amendments of 1977, codified at 42 U.S.C. 7409(d)(2), to provide advice, information and recommendations to the Administrator on the scientific and technical aspects of air quality criteria and National Ambient Air Quality Standards. The SAB is a chartered Federal Advisory Committee, established in 1978 under the authority of the Environmental Research, Development and Demonstration Authorization Act (ERDDAA), codified at 42 U.S.C. 4365, to provide independent scientific and technical peer review, consultation, advice and recommendations to the EPA Administrator on the scientific bases for EPA's actions and programs. Members of the CASAC and the SAB constitute distinguished bodies of non-EPA scientists, engineers, economists, and behavioral and social scientists who are nationally and internationally recognized experts in their respective fields. Members are appointed by the EPA Administrator for a three-year term and serve as Special Government Employees who provide independent expert advice to the agency. Additional information about the CASAC is available at *http://www.epa.gov/casac* and information about the SAB is available at *http://www.epa.gov/sab.*

Expertise Sought for CASAC: Established in 1977 under the Clean Air Act (CAA) Amendments, the chartered CASAC reviews and offers scientific advice to the EPA Administrator on technical aspects of national ambient air quality standards for criteria pollutants (ozone; particulate matter; carbon monoxide; nitrogen oxides; sulfur dioxide; and lead). As required under the CAA section 109(d), CASAC is composed of seven members, with at least one member of the National Academy of Sciences, one physician, and one person representing state air pollution control agencies. The SAB Staff Office is seeking nominations of experts to serve on the CASAC who represent state air pollution control agencies and who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical fields relevant to air pollution and air quality issues. The SAB Staff Office is especially interested in scientists with expertise described above who have knowledge and experience in *air quality relating to criteria pollutants.* For further information about the CASAC membership appointment process and schedule, please contact Mr. Aaron Yeow, DFO, by telephone at (202) 564–2050 or by email at *yeow.aaron@epa.gov.*

Expertise Sought for the SAB: The chartered SAB provides strategic advice to the EPA Administrator on a variety of EPA science and research programs. All the work of SAB committees and panels is under the direction of the chartered SAB. The chartered SAB reviews all SAB committee and panel draft reports and determines whether they are appropriate to send to the EPA Administrator. The SAB Staff Office is seeking nominations of experts to serve on the chartered SAB in the following disciplines as they relate to human health and the environment: *Analytical chemistry; ecological sciences and ecological assessment; economics; engineering; geochemistry; health disparities; health sciences; hydrology; hydrogeology; medicine; microbiology; modeling; pediatrics; public health; risk assessment; social, behavioral and decision sciences; statistics; and toxicology.*

The SAB Staff Office is especially interested in scientists with expertise described above who have knowledge and experience in air quality; agricultural sciences; climate change; drinking water; energy and the environment; water quality; water quantity; water reuse; ecosystem services; community environmental health; sustainability; chemical safety; green chemistry; human health risk assessment; homeland security; and waste and waste management.

For further information about the chartered SAB membership appointment process and schedule, please contact Mr. Thomas Carpenter, DFO, by telephone at (202) 564–4885 or by email at *carpenter.thomas@epa.gov.*

The SAB Staff Office is also seeking nominations for experts for five SAB committees: The Chemical Assessment Advisory Committee; the Drinking Water Committee; the Environmental Economics Advisory Committee; the

Environmental Engineering Committee; and the Radiation Advisory Committee.

(1) The SAB Chemical Assessment Advisory Committee (CAAC) provides advice through the chartered SAB regarding selected toxicological reviews of environmental chemicals available on EPA's Integrated Risk Information System (IRIS). The SAB Staff Office is seeking nominations of experts with experience in chemical assessments. Members should have expertise in one or more of the following disciplines: *Toxicology, including neurotoxicology, developmental/reproductive toxicology, and inhalation toxicology; carcinogenesis; biostatistics; and risk assessment.* For further information about the CAAC membership appointment process and schedule, please contact Dr. Suhair Shallal, DFO, by telephone at (202) 564–2057 or by email at *shallal.suhair@epa.gov.*

(2) The SAB Drinking Water Committee (DWC) provides advice on the scientific and technical aspects of EPA's national drinking water program. The SAB Staff Office is seeking nominations of experts with experience on drinking water issues. Members should have expertise in one or more of the following disciplines: *Environmental engineering; epidemiology; microbiology; public health; and risk assessment.* For further information about the DWC membership appointment process and schedule, please contact Mr. Thomas Carpenter, DFO, by telephone at (202) 564–4885 or by email at *carpenter.thomas@epa.gov.*

(3) The SAB Environmental Economics Advisory Committee (EEAC) provides advice on methods and analyses related to economics, costs, and benefits of EPA environmental programs. The SAB Staff Office is seeking nominations of experts in *environmental economics* to serve on the EEAC. For further information about the EEAC membership appointment process and schedule, please contact Dr. Holly Stallworth, DFO, by telephone at (202) 564–2073 or by email at *stallworth.holly@epa.gov.*

(4) The SAB Environmental Engineering Committee (EEC) provides advice on risk management technologies to control and prevent pollution. The SAB Staff Office is seeking nominations of experts to serve on the EEC with demonstrated expertise in the following disciplines: *Chemical fate and transport; environmental remediation and technology; and geochemistry and geochemical reactions.* For further information about the EEC membership appointment process and schedule, please contact Mr. Edward Hanlon, DFO, by telephone at (202) 564–2134 or by email at *hanlon.edward@epa.gov.*

(5) The Radiation Advisory Committee (RAC) provides advice on radiation protection, radiation science, and radiation risk assessment. The SAB Staff Office is seeking nominations of experts to serve on the RAC with demonstrated expertise in the following disciplines: *Radiation biostatistics; radiation epidemiology; and radiation exposure.* For further information about the RAC membership appointment process and schedule, please contact Mr. Edward Hanlon, DFO, by telephone at (202) 564–2134 or by email at *hanlon.edward@epa.gov.*

Selection Criteria for the CASAC, SAB and the SAB Committees Includes

—Demonstrated scientific credentials and disciplinary expertise in relevant fields;
—Willingness to commit time to the committee and demonstrated ability to work constructively and effectively on committees;
—Background and experiences that would help members contribute to the diversity of perspectives on the committee, *e.g.*, geographic, economic, social, cultural, educational backgrounds, professional affiliations; and other considerations; and
—For the committee as a whole, consideration of the collective breadth and depth of scientific expertise; and a balance of scientific perspectives.

As these committees undertake specific advisory activities, the SAB Staff Office will consider two additional criteria for each new activity: absence of financial conflicts of interest and absence of an appearance of a loss of impartiality.

How To Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to these advisory committees. Individuals may self-nominate. Nominations should be submitted in electronic format (preferred) using the online nomination form under the "Nomination of Experts" category at the bottom of the SAB home page at *http://www.epa.gov/sab.* To be considered, all nominations should include the information requested below. EPA values and welcomes diversity. In an effort to obtain nominations of diverse candidates, EPA encourages nominations of women and men of all racial and ethnic groups.

Nominators are asked to identify the specific committee for which nominees are to be considered. The following information should be provided on the nomination form: contact information for the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's *curriculum vitae;* and a biographical sketch of the nominee indicating current position, educational background; research activities; sources of research funding for the last two years; and recent service on other national advisory committees or national professional organizations. To help the agency evaluate the effectiveness of its outreach efforts, please indicate how you learned of this nomination opportunity. Persons having questions about the nomination process or the public comment process described below, or who are unable to submit nominations through the SAB Web site, should contact the DFO for the committee, as identified above. The DFO will acknowledge receipt of nominations and in that acknowledgement will invite the nominee to provide any additional information that the nominee feels would be useful in considering the nomination, such as availability to participate as a member of the committee; how the nominee's background, skills and experience would contribute to the diversity of the committee; and any questions the nominee has regarding membership. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff Office, will be posted in a List of Candidates on the SAB Web site at *http://www.epa.gov/sab.* Public comments on each List of Candidates will be accepted for 21 days from the date the list is posted. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

Candidates invited to serve will be asked to submit the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency" (EPA Form 3110–48). This confidential form allows EPA to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a loss of impartiality, as defined by Federal regulation. The form may be viewed and downloaded through the "Ethics Requirements for Advisors" link on the SAB home page at *http://www.epa.gov/sab.* This form should not be submitted as part of a nomination.

Dated: March 30, 2016.

Thomas H. Brennan,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2016–07918 Filed 4–5–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Schedule Change and Deletion of Consent Agenda Items From March 31, 2016 Open Meeting

March 31, 2016.

The order of presentations for the Federal Communications Commission Open Meeting on March 31, 2016 and listed in the Commission's Notice of March 24, 2016, has been changed and is listed below. In addition, the Consent Agenda scheduled for consideration at the Open Meeting has been deleted. Items 1, 3, 4 and 5 from the consent agenda have been adopted by the Commission.

Please note that the time for the open meeting is rescheduled from 10:30 a.m. to 12:00 p.m. The prompt and orderly conduct of the Commission's business requires this change and no earlier announcement was practicable.

1	MEDIA	TITLE: Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010 (MB Docket No. 11–43). SUMMARY: The Commission will consider a Notice of Proposed Rulemaking that seeks comment on proposals to expand the amount of and access to video described programming, for the benefit of consumers who are blind or visually impaired.
3	WIRELINE COMPETITION	TITLE: Protecting the Privacy of Customers of Broadband and other Telecommunications Services. SUMMARY: The Commission will consider a Notice of Proposed Rulemaking seeking comment on a proposed framework for ensuring that consumers have the tools they need to make informed choices about how their data is used and when it is shared by their broadband providers.
2	WIRELINE COMPETITION	TITLE: Lifeline and Link Up Reform and Modernization (WC Docket 11–42); Telecommunications Carriers Eligible for Universal Service Support (WC Docket No. 09–197); and Connect America Fund (WC Docket No. 10–90). SUMMARY: The Commission will consider a Third Report and Order, Further Report and Order, and Order on Reconsideration to comprehensively restructure and modernize the Lifeline program to efficiently and effectively connect low-income Americans to broadband, strengthen program oversight and administration, and take additional measures to eliminate waste, fraud, and abuse.

Consent Agenda

1	MEDIA	TITLE: Application for a Minor Change to the Facilities of Station WJKN(AM), Jackson, Michigan; and, Application for a Minor Change to the Facilities of Station KTGG(AM), Okemos, Michigan. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Christian Family Network's seeking review of a Media Bureau dismissal of CFN's informal objection.
2	MEDIA	TITLE: Urban One Broadcasting Network, LLC Application for Construction Permit for New FM Station WURB(FM), at Cross City, Florida; and, Application for Construction Permit for Minor Modification to WURB(FM), Cross City, Florida. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Urban One Broadcasting Network, LLC seeking review of Media Bureau Reconsideration Decision.
3	MEDIA	TITLE: Applications of Powell Meredith Communications Co. and Community Translator Network, LLC for Consent to Assign Construction Permits, K262CM, Needles, California, et al. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Amy Meredith, president of Powell Meredith Communications Company seeking review of a Media Bureau Decision.
4	MEDIA	TITLE: Comparative Consideration of Two Groups of Mutually Exclusive Applications for Permits to Construct New Noncommercial Educational FM Stations. SUMMARY: The Commission will consider a Memorandum Opinion and Order which addresses two groups of mutually exclusive applications for new NCE FM station construction permits.
5	MEDIA	TITLE: Christian Family Network, Inc. Application for Reinstatement and Renewal of License of Station DWOLY(AM), Battle Creek, Michigan; and, Request for Special Temporary Authority to Operate Station DWOLY(AM), Battle Creek, Michigan. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Christian Family Network, Inc. contesting a Media Bureau dismissal and termination of the operating authority of DWOLY(AM).

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–07844 Filed 4–5–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

FCC To Hold Open Commission Meeting, Thursday, March 31, 2016

March 24, 2016.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, March 31, 2016, which is scheduled to commence at 10:30 a.m. in Room TW–C305, at 445 12th Street SW., Washington, DC.

Item No.	Bureau	Subject
1	MEDIA	TITLE: Video Description: Implementation of the Twenty-First Century Communications and Video Accessibility Act of 2010 (MB Docket No. 11–43). SUMMARY: The Commission will consider a Notice of Proposed Rulemaking that seeks comment on proposals to expand the amount of and access to video described programming, for the benefit of consumers who are blind or visually impaired.
2	WIRELINE COMPETITION	TITLE: Lifeline and Link Up Reform and Modernization (WC Docket 11–42); Telecommunications Carriers Eligible for Universal Service Support (WC Docket No. 09–197); and Connect America Fund (WC Docket No. 10–90). SUMMARY: The Commission will consider a Third Report and Order, Further Report and Order, and Order on Reconsideration to comprehensively restructure and modernize the Lifeline program to efficiently and effectively connect low-income Americans to broadband, strengthen program oversight and administration, and take additional measures to eliminate waste, fraud, and abuse.
3	WIRELINE COMPETITION	TITLE: Protecting the Privacy of Customers of Broadband and other Telecommunications Services. SUMMARY: The Commission will consider a Notice of Proposed Rulemaking seeking comment on a proposed framework for ensuring that consumers have the tools they need to make informed choices about how their data is used and when it is shared by their broadband providers.

* * * * * * *

Consent Agenda

The Commission will consider the following subjects listed below as a consent agenda and these items will not be presented individually:

1	MEDIA	TITLE: Application for a Minor Change to the Facilities of Station WJKN(AM), Jackson, Michigan; and, Application for a Minor Change to the Facilities of Station KTGG(AM), Okemos, Michigan. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Christian Family Network's seeking review of a Media Bureau dismissal of CFN's informal objection.
2	MEDIA	TITLE: Urban One Broadcasting Network, LLC Application for Construction Permit for New FM Station WURB(FM), at Cross City, Florida; and, Application for Construction Permit for Minor Modification to WURB(FM), Cross City, Florida. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Urban One Broadcasting Network, LLC seeking review of Media Bureau Reconsideration Decision.
3	MEDIA	TITLE: Applications of Powell Meredith Communications Co. and Community Translator Network, LLC for Consent to Assign Construction Permits, K262CM, Needles, California, et al. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Amy Meredith, president of Powell Meredith Communications Company seeking review of a Media Bureau Decision.
4	MEDIA	TITLE: Comparative Consideration of Two Groups of Mutually Exclusive Applications for Permits to Construct New Noncommercial Educational FM Stations. SUMMARY: The Commission will consider a Memorandum Opinion and Order which addresses two groups of mutually exclusive applications for new NCE FM station construction permits.
5	MEDIA	TITLE: Christian Family Network, Inc. Application for Reinstatement and Renewal of License of Station DWOLY(AM), Battle Creek, Michigan; and, Request for Special Temporary Authority to Operate Station DWOLY(AM), Battle Creek, Michigan. SUMMARY: The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by Christian Family Network, Inc. contesting a Media Bureau dismissal and termination of the operating authority of DWOLY(AM).

The meeting site is fully accessible to people using wheelchairs or other mobility aids. Sign language interpreters, open captioning, and assistive listening devices will be provided on site. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted, but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500; TTY 1–888–835–5322. Audio/Video coverage of the meeting will be broadcast live with open captioning over the Internet from the FCC Live Web page at *www.fcc.gov/live.*

For a fee this meeting can be viewed live over George Mason University's Capitol Connection. The Capitol Connection also will carry the meeting live via the Internet. To purchase these services, call (703) 993–3100 or go to *www.capitolconnection.gmu.edu.*

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2016–07846 Filed 4–5–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Termination: 10342 Sunshine State Community Bank, Port Orange, Florida

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10342, Sunshine State Community Bank, Port Orange, Florida (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Sunshine State Community Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective April 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: April 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–07861 Filed 4–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10084, First Piedmont Bank; Winder, Georgia

Notice is hereby given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for First Piedmont Bank, Winder, Georgia ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of First Piedmont Bank on July 17, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: April 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–07859 Filed 4–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10259, Metro Bank of Dade County; Miami, Florida

Notice is hereby given that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for Metro Bank of Dade County, Miami, Florida ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of Metro Bank of Dade County on July 16, 2010. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: April 1, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–07860 Filed 4–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewals; Comment Request (3064–0001, –0174, –0188 & –0191)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to

comment on the renewal of existing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on the renewal of the information collections described below.

DATES: Comments must be submitted on or before June 6, 2016.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Gary A. Kuiper (202.898.3877), Counsel, MB–3016 or Manny Cabeza (202.898.3767), Counsel MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary Kuiper or Manny Cabeza, at the FDIC address above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently-approved collections of information:

1. *Title:* Charter and Federal Deposit Insurance Application.

OMB Number: 3064–0001.

Affected Public: Banks or savings associations wishing to become FDIC-insured depository institutions.

Frequency of Response: On occasion.

Annual Number of Respondents: 143.

Estimated Time per Response: 125 hours.

Total Annual Burden: 17,875 hours.

General Description: The Federal Deposit Insurance Act requires financial institutions to apply to the FDIC to obtain deposit insurance. This collection provides FDIC with the information needed to evaluate the applications.

2. *Title:* Interagency Guidance on Funding and Liquidity Risk Management.

OMB Number: 3064–0174.

Affected Public: Insured state nonmember banks and state savings associations.

Frequency of Response: Occasionally. (Paragraph 14); Quarterly (Paragraph 20).

Estimated Number of Respondents: 3,947.

Burden Estimate:

	Number of respondents	Average hours per response	Responses per year	Total hours
Paragraph 14 (Record Keeping)				
Large Institutions (over $20 billion in assets)	19	720	1	13,680
Mid-size Institutions ($1 to $20 billion in assets)	329	240	1	78,960
Small Institutions (less than $1 billion in assets)	3,599	80	1	287,920
Paragraph 14 Subtotal	3,947			*380,560*
Paragraph 20 (Reporting)				
All supervised institutions	3,947	4	12	189,456
Total Burden Hours				*570,016*

General Description: The information collection includes reporting and recordkeeping requirements related to sound risk management principles applicable to insured depository institutions. To enable an institution and its supervisor to evaluate the liquidity risk exposure of an institution's individual business lines and for the institution as a whole, the guidance summarizes principles of sound liquidity risk management and advocates the establishment of policies and procedures that consider liquidity costs, benefits, and risks in strategic planning. In addition, the guidance encourages the use of liquidity risk reports that provide detailed and aggregate information on items such as cash flow gaps, cash flow projections, assumptions used in cash flow projections, asset and funding concentrations, funding availability, and early warning or risk indicators. This is intended to enable management to assess an institution's sensitivity to changes in market conditions, the institution's financial performance, and other important risk factors.

3. *Title:* Appraisals for Higher-Priced Mortgage Loans.

OMB Number: 3064–0188.

Affected Public: Insured state nonmember banks and state savings associations.

Frequency of Response: Occasionally.

Estimated Number of Respondents: 2,428.

Burden Estimate:

	Number of respondents	Number of responses	Hours per response	Total burden hours
Review and Provide Copy of Full Interior Appraisal (reporting burden)				
Non-automated responders	809	13	.25	2,629
Automated responders	1,619	13	.08	1,684
Subtotal	2,428			*4,313*
Investigate and Verify Requirement for Second Appraisal (recordkeeping burden)				
Non-automated responders	809	8	.25	1,618
Automated responders	1,619	8	.08	1,036
Subtotal	2,428			*2,654*
Conduct and Provide Second Appraisal (reporting burden)				
Non-automated responders	809	1	.25	202

	Number of respondents	Number of responses	Hours per response	Total burden hours
Automated responders	1,619	1	.08	129
Subtotal	2,428			*331*
Total Annual Burden				*7,298*

General Description: Section 1471 of the Dodd-Frank Act established a new Truth in Lending (TILA) section 129H, which contains appraisal requirements applicable to *higher-risk mortgages* and prohibits a creditor from extending credit in the form of a higher-risk mortgage loan to any consumer without meeting those requirements. A *higher-risk mortgage* is defined as a residential mortgage loan secured by a principal dwelling with an annual percentage rate (APR) that exceeds the average prime offer rate (APOR) for a comparable transaction as of the date the interest rate is set by certain enumerated percentage point spreads. Additionally, 12 CFR part 1026 allows a creditor to make a higher-risk mortgage loan only if certain conditions are met. The creditor must obtain a written appraisal performed by a certified or licensed appraiser who must conduct a physical property visit of the interior of the property. At application, the applicant must be provided with a statement regarding the purpose of the appraisal; a notice that that the creditor will provide the applicant a copy of any written appraisal; and notice that that the applicant may choose to have a separate appraisal conducted at the expense of the applicant. The creditor must also provide the consumer with a free copy of any written appraisals obtained for the transaction at least three business days before closing.

The rule also requires a higher-risk mortgage loan creditor to obtain an additional written appraisal, from a different licensed or certified appraiser, at no cost to the borrower, if: The higher-risk mortgage loan will finance the acquisition of the consumer's principal dwelling; the seller acquired the home within 180 days of signing the agreement to sell the property; and the consumer is purchasing the home for a higher price than the seller paid.

The additional written appraisal generally must include the following information: (1) An analysis of the difference in sale prices (*i.e.,* the sale price paid by the seller and the acquisition price of the property as set forth in the consumer's purchase agreement); (2) Changes in market conditions; and (3) Any improvements made to the property between the date of the previous sale and the current sale.

The information collection requirements are needed to protect consumers and promote the safety and soundness of creditors making higher-risk mortgage loans. This information is used by creditors to evaluate real estate collateral in higher-risk mortgage loan transactions and by consumers entering these transactions.

4. *Title:* Interagency Guidance on Leveraged Lending.

OMB Number: 3064–0191.

Affected Public: Insured state nonmember banks and state savings associations.

Frequency of Response: Occasionally.

Estimated Number of Respondents: 10.

Burden Estimate:

	Number of respondents	Estimated annual frequency	Estimated average hours per response	Estimated total annual burden hours
Implementation Burden				
Recordkeeping burden	1	1	986.7	986.7
Total Implementation Burden				986.7
Ongoing Burden				
Recordkeeping burden	9	1	529.3	4,763.7
Total Ongoing Burden				4,763.7
Total PRA Burden				*5,750.4*

General Description: The Guidance describes expectations for the sound risk management of leveraged lending activities, including the importance for institutions to develop and maintain: (a) Transactions structured to reflect a sound business premise, an appropriate capital structure, and reasonable cash flow and balance sheet leverage; (b) A definition of leveraged lending that facilitates consistent application across all business lines; (c) Well-defined underwriting standards; (d) A credit limit and concentration framework consistent with the institution's risk appetite; (e) Sound MIS that enable management to identify, aggregate, and monitor leveraged exposures and comply with policy across all business lines; (f) Strong pipeline management policies and procedures; and (g) Guidelines for conducting periodic portfolio and pipeline stress tests to quantify the potential impact of economic and market conditions on the institution's asset quality, earnings, liquidity, and capital.

The guidance outlines high-level principles related to safe and sound leveraged lending activities, including underwriting considerations, assessing and documenting enterprise value, risk management expectations for credits awaiting distribution, stress testing expectations and portfolio management, and risk management expectations, all of which will be reviewed during supervisory examinations to assess how well the financial institution is managing its risk. Banks will not be submitting documentation to the FDIC. Rather, FDIC examiners will review this documentation during examinations to assess a bank's management of its risk.

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) The accuracy of the estimates of the burden of the collections of information, including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 31st day of March 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–07819 Filed 4–5–16; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010071–044.

Title: Cruise Lines International Association Agreement.

Parties: Acromas Shipping, Ltd./Saga Shipping; Aida Cruises; AMA Waterways; American Cruise Lines, Inc.; Aqua Expeditions Pte. Ltd.; Australian Pacific Touring Pty Ltd.; Avalon Waterways; Azamara Cruises; Carnival Cruise Lines; CDF Croisieres de France; Celebrity Cruises, Inc.; Celestyal Cruises; Costa Cruise Lines; Compagnie Du Ponant; Croisieurope; Cruise & Maritime Voyages; Crystal Cruises; Cunard Line; Disney Cruise Line; Emerald Waterways; Evergreen Tours; Fred.Olsen Cruise Lines Ltd.; Hapag-Lloyd Kreuzfahrten Gmbh; Hebridean Island Cruises; Holland America Line; Hurtigruten, Inc.; Island Cruises; Lindblad Expeditions Pty Ltd.; Luftner Cruises; Mekong Waterways; MSC Cruises; NCL Corporation; Oceania Cruises; P & O Cruises; P & O Cruises Australia; Paul Gauguin Cruises; Pearl Seas Cruises; Phoenix Reisen Gmbh; Princess Cruises; Pullmantur Cruises Ship Management Ltd.; Regent Seven Seas Cruises; Riviera Tours Ltd.; Royal Caribbean International; Scenic Tours UK Ltd.; Seabourn Cruise Line; SeaDream Yacht Club; Shearings Holidays Ltd.; Silversea Cruises, Ltd.; Star Cruises (HK) Limited; St. Helena Line/Andrew Weir Shipping Ltd.; Swan Hellenic; Tauck River Cruising; The River Cruise Line; Thomson Cruises; Travelmarvel; Tui Cruises Gmbh; Un-Cruises Adventures; Uniworld River Cruises, Inc.; Venice Simplon-Orient-Express Ltd./Belmond; Voyages of Discovery; Voyages to Antiquity (UK) Ltd.; and Windstar Cruises.

Filing Party: Andre Picciurro, Esq. Kaye, Rose & Partners, LLP; Emerald Plaza, 402 West Broadway, Suite 1300; San Diego, CA 92101–3542

Synopsis: The amendment would add language to clarify that the agreement can represent its members before federal and state judiciaries.

Agreement No.: 011223–052.

Title: Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd. and APL Co. PTE Ltd.; (operating as a single carrier); Maersk Line A/S; CMA CGM, S.A.; COSCO Container Lines Company Ltd; Evergreen Line Joint Service Agreement; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha Ltd.; MSC Mediterranean Shipping Company S.A.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; Yangming Marine Transport Corp.; and Zim Integrated Shipping Services, Ltd.

Filing Party: David F. Smith, Esq.; Cozen O'Conner; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment deletes China Shipping Container Lines (Hong Kong) Company Limited and China Shipping Container Lines Company Limited as parties to the agreement.

Agreement No.: 012288–002.

Title: Hoegh/NYK Atlantic/Pacific Space Charter Agreement.

Parties: Hoegh Autoliners AS and Nippon Yusen Kaisha.

Filing Party: Wayne Rohde, Esq.; Cozen O'Connor; 1200 Nineteenth St. NW.; Washington, DC 20006.

Synopsis: The amendment adds the trades between the U.S. West Coast, on the one hand, and Thailand, Taiwan, Indonesia, Malaysia, Brunei, Philippines, Bangladesh, Vietnam, Sri Lanka, Myanmar, Singapore, Australia and New Zealand on the other hand, to the geographic scope of the agreement.

By Order of the Federal Maritime Commission.

Dated: April 1, 2016.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–07890 Filed 4–5–16; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16–0469]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National Program of Cancer Registries Cancer Surveillance System (NPCR CSS, OMB No. 0920–0469, exp. 5/31/2016)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2012, the most recent year for which complete information is available, more than 580,000 people died of cancer and more than 1.5 million were diagnosed with cancer. It is estimated that 13.8 million Americans are currently alive with a history of cancer (2). In the U.S., state-based cancer registries are the only method for systematically collecting and reporting population based information about cancer incidence and outcomes such as survival. These data are used to measure the changing incidence and burden of each cancer; identify populations at increased or increasing risk; target preventive measures; and measure the success or failure of cancer control efforts in the U.S.

In 1992, Congress passed the Cancer Registries Amendment Act which established the National Program of Cancer Registries (NPCR). The NPCR provides support for state-based cancer registries that collect, manage and analyze data about cancer cases. The state-based cancer registries report information to CDC through the National Program of Cancer Registries Cancer Surveillance System (NPCR CSS), (OMB No. 0920–0469 5/31/2016). CDC plans to request OMB approval to continue collecting this information for three years. Data definitions will be updated to reflect changes in national standards for cancer diagnosis and coding, but the number of respondents and the burden per respondent will not change.

The NPCR CSS allows CDC to collect, aggregate, evaluate and disseminate cancer incidence data at the national level. The NPCR CSS is the primary source of information for *United States Cancer Statistics* (*USCS*), which CDC has published annually since 2002. The latest *USCS* report published in 2015 provided cancer statistics for 99% of the United States population from all cancer registries whose data met national data standards. Prior to the publication of *USCS*, cancer incidence data at the national level were available for only 14% of the population of the United States.

The NPCR CSS also allows CDC to monitor cancer trends over time, describe geographic variation in cancer incidence throughout the country, and provide incidence data on racial/ethnic populations and rare cancers. These activities and analyses further support CDC's planning and evaluation efforts for state and national cancer control and prevention. In addition, datasets can be made available for secondary analysis.

Respondents are NPCR-supported central cancer registries (CCR) in 45 U.S. states, 2 territories, and the District of Columbia. Thirty-eight CCR submit data elements specified for the Standard NPCR CSS Report. Ten specialized CCR submit data elements specified for the Enhanced NPCR CSS Report, which includes additional information about treatment and follow-up for cases of breast, colorectal, and chronic myeloid leukemia cases diagnosed in 2011. Each CCR is asked to transmit two data files to CDC per year. The first file, submitted in January, is a preliminary report consisting of one year of data for the most recent year of available data. CDC evaluates the preliminary data for completeness and quality and provides a report back to the CCR. The second file, submitted by November, contains cumulative cancer incidence data from the first diagnosis year for which the cancer registry collected data with the assistance of NPCR funds (*e.g.,* 1995) through 12 months past the close of the most recent diagnosis year (*e.g.,* 2014). The cumulative file is used for analysis and reporting. The burden for each file transmission is estimated at two hours per response. Because cancer incidence data are already collected and aggregated at the state level the additional burden of reporting the information to CDC is small.

All information is transmitted to CDC electronically. Participation is required as a condition of the cooperative agreement with CDC. There are no costs to respondents except their time.

The total estimated annualized burden hours are 192 (152 for the Standard NPCR CSS Report, and 40 for the Enhanced NPCR CSS Report).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Central Cancer Registries in States, Territories and the District of Columbia.	Standard NPCR CSS Report	38	2	2
	Enhanced NPCR CSS Report	10	2	2

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–07806 Filed 4–5–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 16, 2016. The amendment is being made to reflect a change in the *Date and Time* portion of the document. The *Date* of the meeting is changed to May 25, 2016. There are no other changes.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 16, 2016 (81 FR 14115), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on May 24, 2016. On page 14115, in the second column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on May 25, 2016, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: April 1, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–07899 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1099]

Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled "Inorganic Arsenic in Rice Cereals for Infants: Action Level," a supporting document entitled "Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants" (the supporting document), and a risk assessment report entitled "Arsenic in Rice and Rice Products Risk Assessment: Report" (the risk assessment report). The draft guidance, when finalized, will identify for industry an action level for inorganic arsenic in rice cereals for infants that will help protect public health and is achievable with the use of current good manufacturing practice. It also will describe our intended sampling and enforcement approach. The risk assessment report includes a quantitative component (a mathematical model) that estimates occurrence of lung cancer and bladder cancer from long-term exposure to inorganic arsenic in rice and rice products, and a qualitative component that describes our review and evaluation of the scientific literature of certain non-cancer health risks, in certain susceptible life stages, from inorganic arsenic in rice and rice products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance, the supporting document, or the risk assessment report by July 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–1099 for "Inorganic Arsenic in Rice Cereals for Infants: Action Level; Draft Guidance for Industry; Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants; Arsenic in Rice and Rice Products Risk Assessment: Report; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance and the supporting document to the Division of Plant Products and Beverages, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance, supporting document, and risk assessment report.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

Arsenic is present in the environment as a naturally occurring substance or as a result of contamination from human activity. It is found in water, air (*e.g.*, in dust or particulates), soil, and foods. In foods, arsenic may be present as inorganic arsenic (the primary toxic form of arsenic) or organic arsenic. Exposure to inorganic arsenic is associated with many adverse human health effects, including cancer. FDA has been monitoring the levels of total arsenic in foods for decades, as part of our Total Diet Study, an ongoing survey and analysis of the average American diet (Ref. 1), and our Toxic Elements in Food and Foodware and Radionuclides in Food Program (Ref. 2), but only in recent years has methodology been available to FDA laboratories to readily distinguish between inorganic and organic arsenic in a large number and variety of food samples. Arsenic is inadvertently taken up by plants through pathways for essential or beneficial nutrients, and, compared to other cereals, such as oat, wheat, and barley, rice is much more efficient at arsenic accumulation. In 2011, we increased our testing for arsenic in certain foods. In 2012 and 2013, we released analytical results for approximately 1,300 samples of rice and rice products as part of a major effort to understand and manage arsenic-related risks associated with the consumption of these foods in the United States (Ref. 3). More recently, in April 2016 we released the results of our analysis of inorganic arsenic in 526 samples collected in 2014; the samples included rice cereals for infants, as well as non-rice infant cereal and other foods commonly eaten by infants and toddlers (Ref. 4).

We have focused on rice and rice products because evidence from FDA's Total Diet Study revealed that arsenic levels, although varying, tend to be higher in these foods than in others, and rice products are common in the average American diet. Collectively, our sampling indicates that the presence of inorganic arsenic varies widely among and within different categories of rice grain and products made from rice grain, ranging from <1 to 545 parts per billion (ppb) inorganic arsenic.

We are announcing the availability of three documents: (1) A draft guidance for industry entitled "Inorganic Arsenic in Rice Cereals for Infants: Action Level;" (2) a supporting document referenced in the draft guidance entitled "Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants;" and (3) a risk assessment referenced in the draft guidance entitled "Arsenic in Rice and Rice Products Risk Assessment: Report."

In the risk assessment report, we provide quantitative estimates of lung and bladder cancer risk presented by long-term exposure to inorganic arsenic in rice and rice products. We qualitatively address certain non-cancer health risks of exposure to inorganic arsenic in rice and rice products during pregnancy, infancy, and early childhood, periods of high susceptibility to those risks. We also used the mathematical cancer risk model to evaluate the impact of potential mitigation options to reduce the risk. We conducted this risk assessment in consultation with other Federal Agencies, including the National Institute of Environmental Health Science, the FDA National Center for Toxicological Research, and the Environmental Protection Agency. External expert peer review of the risk assessment was conducted; the risk assessment report and peer review documents are available online (Refs. 5, 6, and 7).

The draft guidance identifies an action level for inorganic arsenic in rice cereals for infants of 100 micrograms/kilogram (µg/kg) or 100 parts per billion (ppb), and identifies FDA's intended sampling and enforcement approach. The supporting document reviews data on inorganic arsenic levels in rice cereals for infants, health effects, and achievability, and explains FDA's rationale for identifying an action level for inorganic arsenic in rice cereals for infants of 100 µg/kg.

We conclude that the 100 µg/kg action level will help protect the public health and is achievable with the use of current good manufacturing practice, but we especially welcome comments and information bearing on the achievability and public health benefits and risks of 100 µg/kg, as compared with other potential action levels (including no action level). If the guidance is finalized consistent with the draft, we intend to consider the action level of 100 µg/kg or 100 ppb inorganic arsenic, in addition to other factors, when considering whether to bring enforcement action in a particular case.

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance and the supporting document at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance. Persons with access to the Internet may obtain the risk assessment report at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm.*

III. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. U.S. Food and Drug Administration, "Total Diet Study," 2016, (*http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/ucm2006799.htm*).

2. U.S. Food and Drug Administration, "Toxic Elements in Food and Foodware and Radionuclides in Food Program," 2016, (*http://www.fda.gov/downloads/Food/ComplianceEnforcement/ucm073204.pdf*).

3. U.S. Food and Drug Administration, "Analytical Results from Inorganic Arsenic in Rice and Rice Products Sampling," 2013, (*http://www.fda.gov/downloads/Food/*

FoodborneIllnessContaminants/Metals/UCM352467.pdf).

4. U.S. Food and Drug Administration, "Analytical Results from Inorganic Arsenic in Rice Cereals for Infants, Non-rice Infant Cereal and Other Foods Commonly Eaten by Infants and Toddlers," 2016, (*http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm*).

5. U.S. Food and Drug Administration, "Arsenic in Rice and Rice Products Risk Assessment: Report," 2016, (*http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm485278.htm*).

6. U.S. Food and Drug Administration, "External Peer Review Report. Arsenic in Rice and Rice Products Risk Assessment: Draft Report, Addendum, and Model," 2015, (*http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM486544.pdf*).

7. U.S. Food and Drug Administration, "FDA's Response to External Peer Review on FDA's Arsenic in Rice and Rice Products Risk Assessment: Draft Report (July 2015), Addendum to FDA's Arsenic in Rice and Rice Products Risk Assessment, and Arsenic in Rice and Rice Products Risk Assessment Cancer Model," 2016, (*http://www.fda.gov/downloads/Food/FoodScienceResearch/RiskSafetyAssessment/UCM487230.pdf*).

Dated: April 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07840 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of March 17, 2016. The amendment is being made to reflect a change in the *Date and Time* portion of the document. The *Date* of the meeting is changed to May 24, 2016. There are no other changes.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 17, 2016 (81 FR 14448), FDA announced that a meeting of the Endocrinologic and Metabolic Drugs Advisory Committee would be held on May 25, 2016. On page 14449, in the first column, the *Date and Time* portion of the document is changed to read as follows:

Date and Time: The meeting will be held on May 24, 2016, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: *April 1, 2016.*

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–07906 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Bone, Reproductive and Urologic Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Bone, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 23, 2018.

DATES: Authority for the Bone, Reproductive and Urologic Drugs Advisory Committee will expire on March 23, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *BRUDAC@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Bone, Reproductive and Urologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Bone, Reproductive and Urologic Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of osteoporosis and metabolic bone disease, obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm107572.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION**

CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: April 1, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–07908 Filed 4–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that "[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**." Set forth below is a list of petitions received by HRSA on February 1, 2016, through February 29, 2016. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

a. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by" one of the vaccines referred to in the Table, or

b. "[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading "**FOR FURTHER INFORMATION CONTACT**"), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: March 28, 2016.

James Macrae,

Acting Administrator.

List of Petitions Filed

1. Tessa Skrypek on behalf of D. S., Chippewa Falls, Wisconsin, Court of Federal Claims No: 16–0146V
2. Brandie Sanders, Cypress, Texas, Court of Federal Claims No: 16–0147V
3. Taylor K. Frady on behalf of A. F., Deceased, Piermont, New York, Court of Federal Claims No: 16–0148V
4. Robert Kern, Lower Gwynedd, Pennsylvania, Court of Federal Claims No: 16–0150V
5. Katherine R. Hime, South Bend, Indiana, Court of Federal Claims No: 16–0151V
6. Emma Hicks, Madison, Wisconsin, Court of Federal Claims No: 16–0153V
7. Christina Garber, Honolulu, Hawaii, Court of Federal Claims No: 16–0154V
8. Joseph T. Renfroe, Hiram, Georgia, Court of Federal Claims No: 16–0156V
9. Hannah Mackie, Chicago, Illinois, Court of Federal Claims No: 16–0157V
10. Laura McClary, Sacramento, California, Court of Federal Claims No: 16–0158V

11. Richard Watkins, Arlington, Texas, Court of Federal Claims No: 16–0159V
12. Merrill D. Woods, Grandview, Missouri, Court of Federal Claims No: 16–0160V
13. Debra Byrd, Allston, Massachusetts, Court of Federal Claims No: 16–0162V
14. Tracy Conley, Dublin, Ohio, Court of Federal Claims No: 16–0163V
15. Donna Bartholomew, Walnut Creek, California, Court of Federal Claims No: 16–0164V
16. Anna Johnson, Indianapolis, Indiana, Court of Federal Claims No: 16–0165V
17. John D. Buser, Wyomissing, Pennsylvania, Court of Federal Claims No: 16–0166V
18. Adam Gonzalez and Melissa Lopez on behalf of L. G., Wheat Ridge, Colorado, Court of Federal Claims No: 16–0167V
19. Annette Eberhart, Rancho Mirage, California, Court of Federal Claims No: 16–0169V
20. Linda Kimbrough on behalf of G. A., Vienna, Virginia, Court of Federal Claims No: 16–0170V
21. Phuong Dinh on behalf of C. N., Vienna, Virginia, Court of Federal Claims No: 16–0171V
22. Luis Lao, Orlando, Florida, Court of Federal Claims No: 16–0172V
23. Tarro Dussault, Redding, California, Court of Federal Claims No: 16–0173V
24. Roger M. Steck, North Tonawanda, New York, Court of Federal Claims No: 16–0177V
25. Kathleen Theobald, Vallejo, California, Court of Federal Claims No: 16–0178V
26. Alison Benincasa, Warrington, Pennsylvania, Court of Federal Claims No: 16–0179V
27. Joseph Barcello, Stamford, Connecticut, Court of Federal Claims No: 16–0180V
28. Alison Clark, Radnor, Pennsylvania, Court of Federal Claims No: 16–0181V
29. Christie Kirby, Cheyenne, Wyoming, Court of Federal Claims No: 16–0185V
30. Tyrone Barr, Salem, New Jersey, Court of Federal Claims No: 16–0187V
31. Susan Keller, Madison, Connecticut, Court of Federal Claims No: 16–0188V
32. Rose McAlister, Austin, Texas, Court of Federal Claims No: 16–0189V
33. Kathryn Stacy, Milwaukee, Wisconsin, Court of Federal Claims No: 16–0190V
34. Saurabh Agarwal and Mukta Agarwal on behalf of R. A., Algonquin, Illinois, Court of Federal Claims No: 16–0191V
35. Robert Whaley, Osceola, Wisconsin, Court of Federal Claims No: 16–0192V
36. Melissa Franklin, Boston, Massachusetts, Court of Federal Claims No: 16–0193V
37. Jay P. Bhattacharyya, Vienna, Virginia, Court of Federal Claims No: 16–0195V
38. Angelia R. Andrews, Mountain View, Missouri, Court of Federal Claims No: 16–0196V
39. Tina Marie Copenhagen, Houston, Texas, Court of Federal Claims No: 16–0198V
40. Lu Ann Kendrick, Chiefland, Florida, Court of Federal Claims No: 16–0202V
41. Kyara Galindo, Austin, Texas, Court of Federal Claims No: 16–0203V
42. Daniel Mulvihill, Dallas, Texas, Court of Federal Claims No: 16–0207V
43. Talia Service, Arden, North Carolina, Court of Federal Claims No: 16–0208V
44. Michael A. Halcrow, Seattle, Washington, Court of Federal Claims No: 16–0212V
45. Danny Stotler and Nicole Tracy on behalf of R. S., Salida, Colorado, Court of Federal Claims No: 16–0213V
46. Marni Shapin, Baltimore, Maryland, Court of Federal Claims No: 16–0214V
47. Richard Warner, Saratoga Springs, Florida, Court of Federal Claims No: 16–0216V
48. Sandra Retzlaff, Bloomington, Indiana, Court of Federal Claims No: 16–0217V
49. Evonne Risdall, Santa Barbara, California, Court of Federal Claims No: 16–0218V
50. Allene Larson, Dallas, Texas, Court of Federal Claims No: 16–0219V
51. Consuelo Lory, Maple Shade Township, New Jersey, Court of Federal Claims No: 16–0220V
52. Lindsey Desrosiers, East Greenwich, Rhode Island, Court of Federal Claims No: 16–0224V
53. Elizabeth Schandel, Farmingville, New York, Court of Federal Claims No: 16–0225V
54. Gary Friedland, Teaneck, New Jersey, Court of Federal Claims No: 16–0228V
55. Lana Cooper-Jones, Beverly Hills, California, Court of Federal Claims No: 16–0229V
56. Melissa Wagner, Baraboo, Wisconsin, Court of Federal Claims No: 16–0232V
57. Janet Alles, Portage, Indiana, Court of Federal Claims No: 16–0233V
58. Meghan Lee Stapleton, Tulsa, Oklahoma, Court of Federal Claims No: 16–0234V
59. Mary Sue Allen on behalf of Ronald M. Allen, Washington, District of Columbia, Court of Federal Claims No: 16–0239V
60. Johnnie Evans, Jr. on behalf of Johnnie Evans, Sr., Deceased, Boston, Massachusetts, Court of Federal Claims No: 16–0240V
61. Omary Rocha on behalf of Nestor Rocha, Linwood, New Jersey, Court of Federal Claims No: 16–0241V
62. Jimmon Watson, Alexandria, Virginia, Court of Federal Claims No: 16–0242V
63. Melissa L. Will, Salem, Virginia, Court of Federal Claims No: 16–0244V
64. Oliva Guzman, Eugene, Oregon, Court of Federal Claims No: 16–0246V
65. Scott Kashkin, Chicago, Illinois, Court of Federal Claims No: 16–0247V
66. Carolyn Lanier, Sandusky, Ohio, Court of Federal Claims No: 16–0250V
67. Elizabeth Neeley, Madison, Wisconsin, Court of Federal Claims No: 16–0251V
68. Stephanie Rosenthal, La Jolla, California, Court of Federal Claims No: 16–0253V
69. Kelly Carter, Jacksonville, Florida, Court of Federal Claims No: 16–0254V
70. Cheryl Bourgerie, Simi Valley, California, Court of Federal Claims No: 16–0255V
71. Maureen Li, Arcadia, California, Court of Federal Claims No: 16–0256V
72. Linda Simmonds, Belfair, Washington, Court of Federal Claims No: 16–0258V
73. Gregg Riley, Houston, Texas, Court of Federal Claims No: 16–0262V
74. Alicia Leann Bohn on behalf of B. G., deceased, Piermont, New York, Court of Federal Claims No: 16–0265V
75. Armando Tinoco, Denver, Colorado, Court of Federal Claims No: 16–0266V
76. Laurel Cutter, Beverly Hills, California, Court of Federal Claims No: 16–0267V
77. Duane Morgan, Dresher, Pennsylvania, Court of Federal Claims No: 16–0269V
78. James Kerrigan on behalf of A. K., Linwood, New Jersey, Court of Federal Claims No: 16–0270V
79. Susan Pless, Concord, North Carolina, Court of Federal Claims No: 16–0271V

80. Edward E. Burchett, Jr., Seattle, Washington, Court of Federal Claims No: 16–0274V
81. Christine Toddish, Willowbrook, Illinois, Court of Federal Claims No: 16–0275V
82. Mark V. Davis, Washington, District of Columbia, Court of Federal Claims No: 16–0276V
83. Rosemarie Ward, Sicklerville, New Jersey, Court of Federal Claims No: 16–0278V
84. Patricia Villano, Boston, Massachusetts, Court of Federal Claims No: 16–0279V
85. Velma Finn, Boston, Massachusetts, Court of Federal Claims No: 16–0280V
86. Teresa Bollinger, Boston, Massachusetts, Court of Federal Claims No: 16–0281V
87. Gretchen Kokotovich, Dresher, Pennsylvania, Court of Federal Claims No: 16–0282V
88. Heather Moreau on behalf of Douglas C. Riemer, Milwaukee, Wisconsin, Court of Federal Claims No: 16–0283V
89. Deborah Bynum on behalf of C. J., Phoenix, Arizona, Court of Federal Claims No: 16–0284V
90. Anibal Pinto, Dresher, Pennsylvania, Court of Federal Claims No: 16–0285V
91. Emily Claire Fontenot Quibodeaux on behalf of R. H. Q., Birmingham, Alabama, Court of Federal Claims No: 16–0286V

[FR Doc. 2016–07881 Filed 4–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 81 FR 10874–10875 dated March 2, 2016).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of Federal Assistance Management (RJ). Specifically, this notice: (1) Establishes the Office of Operations and Management (RJA); (2) establishes the Office of Data and Organizational Management (RJB); and (3) updates the functional statement for the Office of Federal Assistance Management (RJ) in its entirety.

Chapter RJ—Office of Federal Assistance Management

Section RJ–00, Mission

The Office of Federal Assistance Management (OFAM) through strategic direction and collaborative efforts provides leadership in the awarding and oversight of federal funds and related activities that advance the HRSA mission.

Section RJ–10, Organization

Delete the organization for the Office of Federal Assistance Management in its entirety and replace with the following:

The Office of Federal Assistance Management (RJ) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Office of Federal Assistance Management includes the following components:

(1) Office of the Associate Administrator (RJ);
(2) Office of Operations Management (RJA);
(3) Office of Data and Organizational Management (RJB);
(4) Division of Financial Integrity (RJ1);
(5) Division of Grants Policy (RJ2);
(6) Division of Grants Management Operations (RJ3); and
(7) Division of Independent Review (RJ4).

Section RJ–20, Functions

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Office of Federal Assistance Management (RJ). Specifically, this notice: (1) Establishes the Office of Operations and Management (RJA); (2) establishes the Office of Data and Organizational Management (RJB); and (3) updates the functional statement for the Office of Federal Assistance Management (RJ) in its entirety.

Delete the function for the Office of Federal Assistance Management, and replace in its entirety.

Office of Federal Assistance Management (RJ)

The Office of Federal Assistance Management (OFAM) provides national leadership in the administration and assurance of the financial integrity of HRSA's programs and provides oversight over HRSA activities to ensure that HRSA's resources are being properly used and protected. Provides leadership, direction, and coordination to all phases of grants policy, administration, and independent review of Competitive grant applications. Specifically: (1) Serves as the Administrator's principal source for grants policy and financial integrity of HRSA programs; (2) exercises oversight over the Agency's business processes related to assistance programs; (3) facilitates, plans, directs, and coordinates the administration of HRSA grant policies and operations; (4) directs and carries out the independent review of grant applications for all of HRSA's programs; (5) exercises the responsibility within HRSA for grant and cooperative agreement receipt, award, and post-award processes; and (6) plans, directs plus manages the electronic systems and business operations that enable staff to perform their day-to-day work.

Office of Operations Management (RJA)

Plans, directs and coordinates OFAM-wide administrative management activities. Specifically: (1) Serves as the principal source for administrative operations advice and assistance; (2) provides guidance and coordinates personnel activities for OFAM; (3) provides organization and management analysis, coordinating the allocation of personnel resources, developing policies and procedures for internal operations, interpreting and implementing OFAM management policies and procedures and systems; (4) develops and coordinates OFAM administrative delegations of authority activities (5) lead, plan, and coordinate all OFAM budgetary activities, such as contracts, procurements and inter-agency agreements, as well as, provides guidance and support to OFAM leadership in these areas; (6) provides OFAM-wide support services such as travel coordination, supply management, equipment utilization, printing, property management, space management, records management, and management reports; (7) coordinates OFAM administrative management activities with other components within HRSA and HHS, and with other Federal agencies, as appropriate; and (8) provides overall support for OFAM's continuity of operations and emergency support.

Office of Data and Organizational Management (RJB)

The Office of Data and Organizational Management provides strategic management and direction for OFAM-wide efforts addressing organizational and staff development, communication and outreach, business operations and data analysis and evaluation. Specifically: (1) Develops and manages multi-year strategic plans; (2) develops and manages OFAM performance measures; (3) provides management guidance on organizational process improvement within OFAM and its divisions as needed; (4) provides guidance on organizational capacity needs for human resources; (5) provides guidance to OFAM managers to plan strategic direction for OFAM staff development, including guidance to OFAM managers for leadership development and staff engagement; (6) develops, implements and manages OFAM's communication plan; (7) provides strategic direction on the use of communication tools, formats, resources to reach internal and external audiences; (8) manages and maintains current data on all electronic sites; (9) provides targeted outreach to non-federal award recipients; and (10) manages and provides guidance on Executive Secretariat processes, Standard Operating Procedures, and routine internal communications.

Division of Financial Integrity (RJ1)

The Division of Financial Integrity: (1) Coordinates Agency-wide efforts addressing HHS's Program Integrity Initiative/Enterprise Risk Management; (2) serves as the Agency's focal point for resolving audit findings on HRSA programs resulting from the Single Audits and special reviews; (3) conducts financial and compliance reviews of non-federal entities use of HRSA funds; (4) conducts the pre-award financial assessment of HRSA non-federal entities; (5) conducts the pre-award and post-award review of grant applicant's and non-federal entities financial soundness and management including accounting systems for managing federal grants; (6) conducts ad hoc studies and reviews related to the financial integrity of the HRSA business processes related to assistance programs; (7) serves as the Agency's liaison with the Office of Inspector General for issues related to HRSA programs; (8) coordinates non-federal entities appeal actions for the Department on HRSA decisions related to HRSA programs; (9) coordinates the preparation of informational reports on high risk non-federal entities; (10) coordinates contractor audit/financial assessment assignments; (11) responds to data requests; (12) serves as the HRSA liaison with the Department on the Single Audit Compliance Supplement update; (13) conducts internal audits; and (14) serves as the outreach to HRSA staff and non-federal entities to increase monitoring efforts for non-federal entities.

Division of Grants Policy (RJ2)

The Division of Grants Policy (DGP) analyzes, develops and implements HRSA's federal assistance award policy in compliance with statutes, regulations, Government-wide administrative requirements and Departmental policy. The DGP recommends internal procedures to ensure consistent and effective stewardship of taxpayer dollars.

Division of Grants Management Operations (RJ3)

The Division of Grants Management Operations exercises responsibility within HRSA for all business aspects of grant and cooperative agreement award and post-award processes, and participates in the planning, development, and implementation of policies and procedures for grants and other federal financial assistance mechanisms. Specifically: (1) Plans, directs and carries out the grants officer functions for all of HRSA's grant programs as well as awarding official functions for various scholarship, loan, and loan repayment assistance programs; (2) participates in the planning, development, and implementation of policies and procedures for grants and cooperative agreements; (3) provides assistance and technical consultation to program offices and grantees in the application of laws, regulations, policies, and guidelines relative to the Agency's grant and cooperative agreement programs; (4) develops standard operating procedures, methods, and materials for the administration of the Agency's grants programs; (5) establishes standards and guides for grants management operations; (6) reviews grantee financial status reports and prepares reports and analyses on the grantee's use of funds; (7) provides technical assistance to applicants and grantees on financial and administrative aspects of grant projects; (8) provides data and analyses as necessary for budget planning, hearings, operational planning, and management decisions; (9) participates in the development of program guidance and instructions for grant competitions; (10) oversees contracts in support of receipt of applications, records management, and grant closeout operations; and (11) supports post-award monitoring and closeout by analyzing payment management system data and working with grants and program office staff.

Division of Independent Review (RJ4)

The Division of Independent Review is responsible for the management and oversight of HRSA's independent review of grant and cooperative agreement applications for funding. Specifically: (1) Plans, directs, and carries out HRSA's independent review of applications for grants and cooperative agreement funding, and assures that the process is fair, open, and competitive; (2) develops, implements, and maintains policies and procedures necessary to carry out the Agency's independent review/peer review processes; (3) provides technical assistance to independent reviewers ensuring that reviewers are aware of and comply with appropriate administrative policies and regulations; (4) provides technical advice and guidance to the Agency regarding the independent review processes; (5) coordinates and assures the development of program policies and rules relating to HRSA's extramural grant activities; and (6) provides HRSA's Offices and Bureaus with the final disposition of all reviewed applications.

Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: March 28, 2016.

James Macrae,

Acting Administrator.

[FR Doc. 2016–07882 Filed 4–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: May 17, 2016, 8:30 a.m. to 5:00 p.m., May 18, 2016, 8:30 a.m. to 5:00 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center (7400 Wisconsin Ave.), Bethesda, Maryland 20814, Telephone: 301 657–1234, Fax: 301 657–6453.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migratory and seasonal agricultural workers and their families and to formulate recommendations for the Secretary of the Department of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from federal officials and experts on agricultural worker issues, including the status of agricultural worker health at the local and national levels. Agenda items are subject to change as priorities indicate.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below at least 10 days prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Esther Paul, MBBS, MA, MPH., Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, 16N38B, Maryland 20857; Phone number: (301) 594–4496.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–07909 Filed 4–5–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding a meeting to continue discussions and possibly develop recommendations regarding People Living with HIV/AIDS. During this meeting, PACHA members will have discussions regarding Health System Transformations, community approaches to implementing the Updated National HIV/AIDS Strategy, and a panel making the case for food as medicine. The meeting will be open to the public.

DATES: The meeting will be held on May 24, 2016, from 9:00 a.m. to approximately 5:00 p.m. (ET) and May 25, 2016, from 9:00 a.m. to approximately 12:00 p.m. (ET).

ADDRESSES: 200 Independence Avenue SW., Washington, DC 20201 in the Penthouse (eighth floor), Room 800.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue SW., Room 443H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 205–1178 or *Caroline.Talev@hhs.gov.* More detailed information about PACHA can be obtained by accessing the Council's page on the AIDS.gov site at *www.aids.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996. In a memorandum, dated July 13, 2010, and under Executive Order 13703, dated July 30, 2015, the President gave certain authorities to the PACHA for implementation of the National HIV/AIDS Strategy for the United States (Strategy). PACHA is currently operating under the authority given in Executive Order 13708, dated September 30, 2015.

PACHA provides advice, information, and recommendations to the Secretary regarding programs, policies, and research to promote effective treatment, prevention, and cure of HIV disease and AIDS, including considering common co-morbidities of those infected with HIV as needed, to promote effective HIV prevention and treatment and quality services to persons living with HIV disease and AIDS.

Substantial progress has been made in addressing the domestic HIV epidemic since the Strategy was released in July 2010. Under Executive order 13703, the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) was released. PACHA shall contribute to the federal effort to improve HIV prevention and care.

The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda for the upcoming meeting will be posted on the AIDS.gov Web site at *www.aids.gov/pacha.*

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at *Caroline.Talev@hhs.gov.* Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on May 17, 2016. Members of the public will have the opportunity to provide comments at the meeting. Any individual who wishes to participate in the public comment session must register with Caroline Talev at *Caroline.Talev@hhs.gov* by close of business on May 17, 2016; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Public comment will be limited to two minutes per speaker. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business on May 17, 2016.

Dated: March 22, 2016.

B. Kaye Hayes,

Executive Director, Presidential Advisory Council on HIV/AIDS.

[FR Doc. 2016–07880 Filed 4–5–16; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License for Commercialization: Boron Neutron Capture Therapy for Brain Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in: HHS Ref. No. E–135–2015/0, U.S. Provisional Patent Application No. 62/155,085, filed April 30, 2015, entitled "Boron Mimics Of Amino Acids And Uses Thereof," to Beijing Lanyears Communication

Technology, Ltd., a company formed under the laws of the People's Republic of China and having its principle place of business in Beijing, China.

The contemplated exclusive license may be limited to boron neutron capture therapy for brain tumors.

DATES: Only written comments and/or applications for a license that are received by NIH at the address indicated below on or before April 21, 2016 will be considered.

ADDRESSES: Requests for a copy of any unpublished patent application, inquiries, objections to this notice, comments and other requests relating to the contemplated license should be directed to: Michael Shmilovich, Esq., CLP, Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–5019, or *shmilovm@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention pertains to boramino acid compounds that can be used as imaging agents for positron emission tomography of cancer or for boron neutron capture therapy. Mimetics created by substituting the carboxylate group (-COO-) of an amino acid with trifluoroborate (-BF3-) are metabolically stable and allow for the use of fluorine-18 (^{18}F) as the radiolabel (*e.g.,* trifluoroborate phenylalanine (B-Phe)). Using boramino acid for ^{18}F-labeling allows for integrating the ^{18}F radiolabel into the core molecular backbone rather than the side-chains thus increasing the agent's target specificity. There is a direct relationship between amino acid uptake and cancer cell replication, where the uptake is extensively upregulated in most cancer cells. This uptake increases as cancer progresses, leading to greater uptake in high-grade tumors and metastases. Amino acids act as signaling molecules for proliferation and may also reprogram metabolic networks in the buildup of biomass. This invention provides for an unmet need for traceable amino acid mimics, including those based on naturally-occurring amino acids, which may be non-invasively detected by imaging technology, including for clinical diagnosis or BNCT. Boron neutron capture therapy (BNCT) is based on the nuclear capture and fission reactions that occur when non-radioactive boron-10 (^{10}B, approximately 20% of natural elemental boron), is irradiated and thus activated with neutrons of the appropriate energy to yield excited boron-11 ($^{11}B^*$). This isotope turn decays into high energy alpha particles ("stripped" down ^4He nuclei) and high energy lithium-7 (^7Li) nuclei. Both the emitted alpha particles and the lithium ions are close proximity reactions, *i.e.,* at a range of approximately 5–9 μm; the diameter of a target cell. The energies produced in this ionization and radio-decay is cytotoxic and thus exploited as the basis for cancer radiotherapy. The success of BNCT is dependent on the selective delivery of sufficient amounts of ^{10}B to the tumor site with only small amounts localized in the surrounding normal tissues thus sparing normal tissue from the nuclear capture and fission reactions.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 1, 2016.

Michael Shmilovich,

Senior Licensing and Patent Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

[FR Doc. 2016–07865 Filed 4–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License for Commercialization: Boron Neutron Capture Therapy for Skin Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a worldwide exclusive license to practice the inventions embodied in: HHS Ref. No. E–135–2015/0, U.S. Provisional Patent Application No. 62/155,085, filed April 30, 2015, entitled "Boron Mimics Of Amino Acids And Uses Thereof," to Beijing Lanyears Communication Technology, Ltd., a company formed under the laws of the People's Republic of China and having its principle place of business in Beijing, China.

The contemplated exclusive license may be limited to boron neutron capture therapy for skin cancer.

DATES: Only written comments and/or applications for a license that are received by NIH at the address indicated below on or before April 21, 2016 will be considered.

ADDRESSES: Requests for a copy of any unpublished patent application, inquiries, objections to this notice, comments and other requests relating to the contemplated license should be directed to: Michael Shmilovich, Esq., CLP, Senior Licensing and Patent Manager, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–5019, or *shmilovm@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention pertains to boramino acid compounds that can be used as imaging agents for positron emission tomography of cancer or for boron neutron capture therapy. Mimetics created by substituting the carboxylate group (-COO-) of an amino acid with trifluoroborate (-BF3-) are metabolically stable and allow for the use of fluorine-18 (^{18}F) as the radiolabel (*e.g.,* trifluoroborate phenylalanine (B-Phe)). Using boramino acid for ^{18}F-labeling allows for integrating the ^{18}F radiolabel into the core molecular backbone rather than the side-chains thus increasing the agent's target specificity. There is a direct relationship between amino acid uptake and cancer cell replication, where the uptake is extensively upregulated in most cancer cells. This uptake increases as cancer progresses, leading to greater uptake in high-grade tumors and metastases. Amino acids act as signaling molecules for proliferation and may also reprogram metabolic networks in the buildup of biomass. This invention provides for an unmet need for traceable amino acid mimics, including those based on naturally-occurring amino acids, which may be non-invasively detected by imaging technology, including for clinical diagnosis or BNCT. Boron neutron capture therapy (BNCT) is based on the nuclear capture and fission reactions that occur when non-radioactive boron-10 (^{10}B, approximately 20% of natural elemental boron), is irradiated and thus activated with neutrons of the appropriate energy to yield excited boron-11 ($^{11}B^*$). This isotope turn decays into high energy alpha particles ("stripped" down ^{4}He nuclei) and high energy lithium-7 (^{7}Li) nuclei. Both the emitted alpha particles and the lithium ions are close proximity reactions, *i.e.*, at a range of approximately 5–9 µm; the diameter of a target cell. The energies produced in this ionization and radio-decay is cytotoxic and thus exploited as the basis for cancer radiotherapy. The success of BNCT is dependent on the selective delivery of sufficient amounts of ^{10}B to the tumor site with only small amounts localized in the surrounding normal tissues thus sparing normal tissue from the nuclear capture and fission reactions.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 1, 2016.

Michael Shmilovich,

Senior Licensing and Patent Manager, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute.

[FR Doc. 2016–07864 Filed 4–5–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2016–0027]

Privacy Act of 1974; Department of Homeland Security, U.S. Customs and Border Protection, DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current DHS system of records titled, "DHS/U.S. Customs and Border Protection (CBP)–014 Regulatory Audit Archive System (RAAS) System of Records" (73 FR 77807, December 19, 2008). This system of records allows DHS/CBP to collect and maintain records on individuals subject to regulatory audits of customs brokers, importers, and other parties involved in international trade activities. CBP is updating this system of records notice to reflect changes to its authorities, category of records, and routine uses. Specifically, these changes include expanding the category of records to permit the collection of Employer Identification Numbers (EINs) or Social Security numbers (SSNs), also known as a Federal Taxpayer Identifying Number, and business records associated with the audit from customs brokers, importers, and other parties via merchandise entry documentation. CBP is clarifying the authorities section to include updated and more narrowly tailored authorities to permit the collection of EIN or SSN. CBP is making non-substantive edits to the Routine Uses A–G to align with previously published Departmental Systems of Records Notices (SORNs). Lastly, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

Additionally, DHS is issuing a Notice of Proposed Rulemaking to reduce the current exemptions for this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. The previously issued Final Rule for DHS/CBP–014 RAAS (Aug. 31, 2009, 74 FR 45076) remains in effect until a new Final Rule is issued. This updated system will be included in the DHS inventory of record systems.

DATES: Submit comments on or before May 6, 2016. This updated system will be effective May 6, 2016.

ADDRESSES: You may submit comments, identified by docket number DHS–2016–0027 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: John Connors, (202) 344–1610, Privacy Officer, U.S. Customs and Border Protection, Privacy and Diversity Office, 1300 Pennsylvania Ave. NW., Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP) proposes to update and reissue a current DHS system of records titled, "DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records."

DHS/CBP conducts regulatory audits in support of its oversight of customs brokers licensed by DHS/CBP pursuant to 19 U.S.C. 1641 to act as agents for importers in the entry of merchandise and payment of duties and fees. This system of records covers records about importers and other parties engaged in international trade activities that are the subject of a regulatory audit or are identified in and related to the scope of an audit report.

As a result of a biennial review of this SORN, DHS/CBP is updating the categories of records to include the collection of EINs or SSNs, also known as Federal Taxpayer Identifying Number, pursuant to 19 CFR 24.5, 19 CFR 149.3, and E.O. 9397, *as amended* by E.O. 13478. DHS/CBP collects this additional data to align RAAS with information provided by importers through the DHS/CBP Automated Commercial Environment System (ACE) data-source. DHS/CBP is also clarifying the category of records to include business and audit records collected or created as part of the audit process.

DHS/CBP is clarifying the authorities section to include updated and more narrowly tailored authorities to permit the collection of EIN or SSN. 19 CFR 24.5 and 19 CFR 149.3 require that DHS/CBP collect Federal Taxpayer Identifying Numbers in association with services resulting in issuance of a bill or refund check upon adjustment of a cash collection or to document entities that are liable for payment of all duties and responsible for meeting all statutory or regulatory requirements incurred as a result of importation. Individuals or entities that do not have a SSN may submit an EIN in lieu of the SSN for merchandise entry purposes.

DHS/CBP is making non-substantive edits to the Routine Uses A–G to align with previously published Departmental SORNs. This notice also includes non-substantive changes to simplify the formatting and texts of the previously published notice.

Consistent with DHS's information sharing mission, information stored in DHS/CBP–014 RAAS may be shared with other DHS Components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, DHS/CBP may share information with appropriate Federal, State, local, tribal, territorial, foreign, or international government agencies consistent with the routine uses set forth in this system of records notice.

Additionally, DHS is issuing a Notice of Proposed Rulemaking to reduce the current exemptions for this system of records from certain provisions of the Privacy Act elsewhere in the **Federal Register**. The previously issued Final Rule for DHS/CBP–014 RAAS (Aug. 31, 2009; 74 FR 45076) remains in effect until a new Final Rule is issued. This updated system will be included in the DHS inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/CBP–014 Regulatory Audit Archive System (RAAS) System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM OF RECORDS:

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)-014.

SYSTEM NAME:

DHS/CBP–014 Regulatory Audit Archive System (RAAS).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in the Regulatory Audit Management Information System (RAMIS) located at the U.S. Customs and Border Protection Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include importers and other parties engaged in international trade activities that are the subject of a regulatory audit or are identified in and related to the scope of an audit report.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of individuals covered by this system include:

- Individual's name, including names of officers of customs broker firms or other business entities engaged in international trade and identified as a subject of an audit or related to the scope of an audit;
- Importer of Record (IR) Number;
- Dun and Bradstreet, Inc. DUN numbers;
- Business records associated with the audit;
- Email address;
- Phone number;
- Employer Identification Number (EIN) or Social Security number (SSN), also known as Federal Taxpayer Identifying Number;
- Audit reports of subject accounts and records;
- Correspondence with the subject of the audits and related parties:
- Congressional inquiries concerning customs brokers or other audit subjects and disposition made of such inquiries; and
- License and permit numbers and dates issued and district or port covered.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

6 U.S.C. 115(a)(1) and 213(b)(2); 19 U.S.C. ch. 4; 19 U.S.C. 1508, 1509, 1592, and 1641; 19 CFR parts 24.5, 111, 143, 149.3, 163; 31 U.S.C. 3729; and E.O. 9397, *as amended* by E.O. 13478.

PURPOSE(S):

The purpose of this system is to collect and maintain records on the regulatory audits of customs brokers, licensed by CBP pursuant to 19 U.S.C. 1641, to act as agents for importers in the entry of merchandise and payment of duties and fees, and other persons or business entities engaged in international trade.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any Component thereof;

2. Any employee or former employee of DHS in his/her official capacity;

3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or

integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To an appropriate Federal, State, local, tribal, foreign, or international agency, if the information is relevant and necessary to a requesting agency's decision concerning the hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit, or if the information is relevant and necessary to a DHS decision concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit and disclosure is appropriate to the proper performance of the official duties of the person making the request.

I. To a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena from a court of competent jurisdiction.

J. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

Disclosure to consumer reporting agencies:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

DHS/CBP stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

RETRIEVABILITY:

DHS/CBP may retrieve records by name or other (alphanumeric) personal identifier.

SAFEGUARDS:

DHS/CBP safeguards records in this system according in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/CBP has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

DHS/CBP maintains regulatory audit records in accordance with N1–36–86–1 approved by NARA on November 9, 1989. CBP maintains regulatory reports and company findings on-site for one year and then transfers the records to the Federal Records Center (FRC), which destroys the records after ten (10) years. CBP maintains regulatory audit subject records on-site for one year and transfers the files to the FRC, which destroys the records after three years.

SYSTEM MANAGER AND ADDRESS:

Executive Director, Regulatory Audit, U.S. Customs and Border Protection, 1717 H Street—6th Floor, Washington, DC 20229.

NOTIFICATION PROCEDURE:

Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the DHS Chief Freedom of Information Act (FOIA) Officer or CBP's FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under "Contacts." If an individual believes more than one Component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Office at *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which Component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS Component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his or her records.

Without the above information, the Component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

The information contained in this system of records originates in connection with customs broker audits and audits of other persons engaged in international commerce conducted by the regulatory audit staffs. The audits may be supplemented with information furnished by the Office of the Chief Counsel or its field offices, Office of International Trade—Regulations and Rulings, and the Office of Investigations, U.S. Immigration and Customs Enforcement. These audits include examination of records pertaining to brokers and importers (including their clients), and other persons engaged in international trade activities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

DHS/CBP is not requesting an exemption with respect to information maintained in the system as it relates to data submitted by or on behalf of a subject of an audit. Information in the system may be shared pursuant to the exceptions under the Privacy Act (5 U.S.C. 552a(b)) and the above routine uses. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agency has sought particular records may affect ongoing law enforcement activity. Therefore, pursuant to 5 U.S.C. 552a(k)(2), DHS will claim exemption from sec. (c)(3) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information.

Dated: March 22, 2016.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–07893 Filed 4–5–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2016–0024]

Privacy Act of 1974: Department of Homeland Security/ALL–030 Use of the Terrorist Screening Database System of Records

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current Department-wide system of records titled, "Department of Homeland Security (DHS)/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records," 76 FR 39408, July 6, 2011. This system of records allows DHS to maintain a synchronized copy of the Department of Justice's (DOJ) Federal Bureau of Investigation's (FBI) Terrorist Screening Database (TSDB), which includes categories of individuals covered by DOJ/FBI–019, "Terrorist Screening Records Center System," 72 FR 77846 (Dec. 14, 2011). DHS maintains a synchronized copy to automate and simplify the transmission of information in the Terrorist Screening Database to DHS and its Components. With this updated notice, DHS is reducing the number of claimed exemptions, pursuant to a concurrently published Final Rule elsewhere in the **Federal Register**. A detailed description of the recent changes to the DHS/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records is published elsewhere in the **Federal Register** at 81 FR 3811 (Jan. 22, 2016).

DHS is issuing a new Final Rule concurrently with this notice. The existing Final Rule for Privacy Act exemptions will continue to apply until the new Final Rule is published. This updated system will be included in DHS's inventory of record systems.

DATES: Submit comments on or before May 6, 2016. This updated system will be effective May 6, 2016.

ADDRESSES: You may submit comments, identified by docket number DHS–2016–0024 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions and privacy issues please contact: Karen L. Neuman (202–343–1717), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to update and reissue a current Department-wide system of records titled, "Department of Homeland Security (DHS)/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records," 76 FR 39408, July 6, 2011. This system of records allows DHS to maintain a synchronized copy of the Department of Justice's (DOJ) Federal Bureau of Investigation's (FBI) Terrorist Screening Database (TSDB), which includes categories of individuals covered by DOJ/FBI–019, "Terrorist Screening Records Center System," 72 FR 77846 (Dec. 14, 2011). DHS maintains a synchronized copy to automate and simplify the transmission of information in the Terrorist Screening Database to DHS and its Components. With this updated notice, DHS is reducing the number of claimed exemptions, pursuant to a concurrently published Final Rule elsewhere in the **Federal Register**. A detailed description of the recent changes to the categories of individuals in the DHS/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records is published elsewhere in the **Federal Register** at 81 FR 3811 (Jan. 22, 2016).

DHS is issuing a new Final Rule concurrently with this notice. The existing Final Rule for Privacy Act exemptions, 75 FR 55335 (Dec. 29, 2011) will continue to apply until the new Final Rule is published. This updated system will be included in DHS's inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

(DHS)/ALL–030

SYSTEM OF RECORDS:

Department of Homeland Security (DHS)/ALL–030

SYSTEM NAME:

DHS/ALL–030 Use of the Terrorist Screening Database (TSDB) System of Records

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained at DHS and Component Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include:

(a) Individuals known or suspected to be or have been engaged in conduct constituting, in preparation for, in aid of, or related to terrorism ("known or suspected terrorists");

(b) Individuals who are foreign nationals or lawful permanent resident aliens and who are excludable from the United States based on their familial relationship, association, or connection with a known or suspected terrorist as described in sec. 212(a)(3)(B) of the Immigration and Nationality Act of 1952 ("INA exceptions");

(c) Individuals who were officially detained during military operations, but not as Enemy Prisoners of War, and who have been identified to pose an actual or possible threat to national security ("military detainees"); and

(d) Individuals known or suspected to be or have been engaged in conduct constituting, in aid of, or related to transnational organized crime, thereby posing a possible threat to national security ("transnational organized crime actors").

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

1. Identifying biographic information, such as name, date of birth, place of birth, passport or driver's license information, and other available identifying particulars used to compare the identity of an individual being screened with a subject in the TSDB;
2. Biometric information, such as photographs, fingerprints, or iris images, and associated biographic and contextual information;
3. References to or information from other government law enforcement and intelligence databases, or other relevant databases that may contain terrorism or national security information, such as unique identification numbers used in other systems;
4. Information collected and compiled to maintain an audit trail of the activity of authorized users of WLS information systems; and
5. System-generated information, including metadata, archived records and record histories from WLS.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Homeland Security Act of 2002, Pub. L. 107–296, 116 Stat. 2135; The Tariff Act of 1930, Pub. L. 71–361, 46 Stat. 741, as amended; The Immigration and Nationality Act; 49 U.S.C. 114, 5103a, 40113, ch. 49 and 46105; Homeland Security Presidential Directive/HSPD–6, "Integration and Use of Screening Information to Protect Against Terrorism" (Sept. 16, 2003); Homeland Security Presidential Directive/HSPD–11, "Comprehensive Terrorist-Related Screening Procedures" (Aug. 27, 2004); National Security Presidential Directive/NSPD–59/Homeland Security Presidential Directive/HSPD–24, "Biometrics for Identification and Screening to Enhance National Security" (June 5, 2008); E.O. 13388, "Further Strengthening the Sharing of Terrorism Information to Protect Americans," 70 FR 62023 (Oct. 25, 2005); Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. 108–458, 118 Stat 3638; National Security Act of 1947, Pub. L. 235, 61 Stat. 495, as amended; and 28 U.S.C. 533.

PURPOSE(S):

DHS and its Components collect, use, maintain, and disseminate information in the DHS Watchlist Service (WLS) to facilitate DHS mission-related functions, such as counterterrorism, law enforcement, border security, and inspection activities. The TSDB data, which includes personally identifiable information (PII), is necessary for DHS to effectively and efficiently assess the risk or threat posed by a person for the conduct of its mission.

The Federal Bureau of Investigation's (FBI's) Terrorist Screening Center (TSC) provides a near real time, synchronized version of the TSDB to DHS in order to improve the timeliness and governance of watchlist data exchanged between the FBI's TSC and DHS and its Component systems that currently use TSDB data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ)/FBI/TSC in order to receive confirmations that the information has been appropriately transferred and any other information related to the reconciliation process so that DHS is able to maintain a synchronized copy of the TSDB.

DHS will share information contained in this system to Components internal to DHS pursuant to subsec. 552a(b)(1) of the Privacy Act, and subsequently may be shared externally outside DHS at the programmatic level pursuant to routine uses described in the following published system of records notices:

(1) DHS/TSA–002 Transportation Security Threat Assessment System (T–STAS), 79 FR 46862, Aug. 11, 2014;

(2) DHS/TSA–019 Secure Flight Records, 80 FR 223, Jan. 5, 2015;

(3) DHS/CBP–011 TECS, 73 FR 77778, Dec. 19, 2008;

(4) DHS/CBP–006, Customs and Border Protection Automated Targeting System, 77 FR 30297, May 22, 2012;

(5) DHS/US–VISIT–004, DHS Automated Biometric Identification System (IDENT), 72 FR 31080, June 5, 2007;

(6) DHS/IA–001, Office of Intelligence and Analysis (I&A) Enterprise Records System, 73 FR 28128, May 15, 2008;

(7) DHS/ICE–009, ICE External Investigations, 75 FR 404, Jan. 5, 2010; and

(8) DHS/USCIS–006 Fraud Detection and National Security Records, 77 FR 47411, Aug. 8, 2012.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

DHS stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on servers, magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

DHS may retrieve records by name or other personal identifier.

SAFEGUARDS:

DHS safeguards records in this system in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

The WLS maintains a near real-time feed of the TSDB, and does not retain historical copies of the TSDB. The WLS is synchronized with the TSDB. When the FBI/TSC adds, modifies, or deletes data from TSDB, WLS duplicates these functions almost simultaneously, and that information is then passed to DHS and its authorized Component systems. DHS does not manipulate the data within TSDB feed received by WLS. The authorized DHS Component that is screening individuals will maintain, separate from WLS, a record of a match or possible match with TSDB and DHS will retain this information in accordance with the DHS Component specific SORNs identified in this notice.

SYSTEM MANAGER AND ADDRESS:

Executive Director, Passenger Systems Program Directorate, Office of Information and Technology, U.S. Customs and Border Protection, 7400 Fullerton Rd, Springfield, VA 22153.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, DHS and its Components will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under "contacts." If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer and Chief FOIA Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer at *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which Component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his or her records.

Without the above information, the Component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

In addition, if individuals are uncertain what agency handles the information, they may seek redress through the DHS Traveler Inquiry Redress Program (DHS TRIP), 72 FR 2294, Jan. 18, 2007. Individuals who believe they have been improperly denied entry, refused boarding for transportation, or identified for additional screening by DHS may submit a redress request through DHS TRIP. The DHS TRIP is a single point of contact for individuals who have inquiries or seek resolution regarding difficulties they experienced during their travel screening at transportation hubs such as airports and train stations or crossing U.S. borders. Redress requests should be sent to: DHS Traveler Redress Inquiry Program, 601 South 12th Street, TSA–901, Arlington, VA 20598 or online at *http://www.dhs.gov/trip* and at *http://www.dhs.gov.*

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

Records are received from the FBI's Terrorist Screening Center, specifically records covered by DOJ/FBI–019, "Terrorist Screening Records Center System," 72 FR 77846 (Dec. 14, 2011).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act, subject to the limitations set forth in 5 U.S.C. 552a(c)(3) and (c)(4); (d); (e)(1), (e)(2), (e)(3), (e)(5), (e)(8); and (g) pursuant to 5 U.S.C. 552a(j)(2).

Dated: March 22, 2016.

Karen L. Neuman,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2016–07895 Filed 4–5–16; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FW–HQ–LE–2016–N069; FF09L00200–FX–LE18110900000]

Proposed Information Collection; Captive Wildlife Safety Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (U.S. Fish and Wildlife Service) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on August 31, 2016. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: To ensure that we are able to consider your comments on this IC, we must receive them by June 6, 2016.

ADDRESSES: Send your comments on the IC to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS BPHC, 5275

Leesburg Pike, Falls Church, VA 22041–3803 (mail); or *hope_grey@fws.gov* (email). Please include "1018–0129" in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Hope Grey at *hope_grey@fws.gov* (email) or 703–358–2482 (telephone).

SUPPLEMENTARY INFORMATION:

I. Abstract. The Captive Wildlife Safety Act (CWSA) amends the Lacey Act by making it illegal to import, export, buy, sell, transport, receive, or acquire, in interstate or foreign commerce, live lions, tigers, leopards, snow leopards, clouded leopards, cheetahs, jaguars, or cougars, or any hybrid combination of any of these species, unless certain exceptions are met. There are several exemptions to the prohibitions of the CWSA, including accredited wildlife sanctuaries.

There is no requirement for wildlife sanctuaries to submit applications to qualify for the accredited wildlife sanctuary exemption. Wildlife sanctuaries themselves will determine if they qualify. To qualify, they must meet all of the following criteria:

- Approval by the United States Internal Revenue Service (IRS) as a corporation that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986, which is described in sections 501(c)(3) and 170(b)(1)(A)(vi) of that code.
- No engagement in commercial trade in the prohibited wildlife species, including offspring, parts, and products.
- No propagation of the prohibited wildlife species.
- No direct contact between the public and the prohibited wildlife species.

The basis for this information collection is the recordkeeping requirement that we place on accredited wildlife sanctuaries. We require accredited wildlife sanctuaries to maintain complete and accurate records of any possession, transportation, acquisition, disposition, importation, or exportation of the prohibited wildlife species as defined in the CWSA (50 CFR 14, subpart K). Records must be up to date and include: (1) Names and addresses of persons to or from whom any prohibited wildlife species has been acquired, imported, exported, purchased, sold, or otherwise transferred; and (2) dates of these transactions. Accredited wildlife sanctuaries must:

- Maintain these records for 5 years.
- Make these records accessible to Service officials for inspection at reasonable hours.
- Copy these records for Service officials, if requested.

II. Data

OMB Control Number: 1018–0129.

Title: Captive Wildlife Safety Act, 50 CFR 14.250–14.255.

Service Form Number: None.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Accredited wildlife sanctuaries.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Ongoing.

Estimated Number of Respondents: 750.

Estimated Number of Responses: 750.

Completion Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 750.

Estimated Annual Nonhour Burden Cost: None.

III. Comments

We invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this IC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: April 1, 2016.

Tina A. Campbell,

Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.

[FR Doc. 2016–07841 Filed 4–5–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCOS00000 L10100000.BN0000 16X]

Notice of Public Meetings, Southwest Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Southwest Resource Advisory Council (RAC) is scheduled to meet as indicated below.

DATES: The Southwest RAC meeting will be held on June 10, 2016, in Mancos, Colorado.

ADDRESSES: The Southwest RAC meeting will be held June 10 at the Mancos Community Building, 130 Grand Ave., Mancos, CO 81328. The meeting will begin at 9 a.m. and adjourn at approximately 4 p.m. A public comment period regarding matters on the agenda will be held at 11:30 a.m.

FOR FURTHER INFORMATION CONTACT: Shannon Borders, Public Affairs Specialist, 970–240–5300; 2505 S. Townsend Ave., Montrose, CO 81401. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Southwest RAC advises the Secretary of the Interior, through the BLM, on a variety of public land issues in Colorado. Topics of discussion for all Southwest RAC meetings may include field manager and working group reports, recreation, fire management, land use planning, invasive species management, energy and minerals management, travel management, wilderness, land exchange proposals, cultural resource management and other issues as appropriate. These meetings are open to the public. The public may present written comments to the RACs. Each formal RAC meeting will also have time, as identified above, allocated for hearing public comments. Depending on the number of people wishing to comment and time available, the time for individual oral comments may be limited.

Ruth Welch,

BLM Colorado State Director.

[FR Doc. 2016–07866 Filed 4–5–16; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO956000 L14400000.BJ0000 16X]

Notice of Filing of Plats of Survey; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Filing of Plats of Survey; Colorado.

SUMMARY: The Bureau of Land Management (BLM) Colorado State Office is publishing this notice to inform the public of the intent to officially file the survey plats listed below and afford a proper period of time to protest this action prior to the plat filing. During this time, the plats will be available for review in the BLM Colorado State Office.

DATES: Unless there are protests of this action, the filing of the plats described in this notice will happen on May 6, 2016.

ADDRESSES: BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, CO 80215–7093.

FOR FURTHER INFORMATION CONTACT: Randy Bloom, Chief Cadastral Surveyor for Colorado, (303) 239–3856.

Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The plat and field notes of the dependent resurvey in Township 27 South, Range 55 West, Sixth Principal Meridian, Colorado, were accepted on December 9, 2015.

The plat and field notes of the dependent resurvey and survey in Township 13 South, Range 69 West, Sixth Principal Meridian, Colorado, were accepted on January 7, 2016.

The field notes of the remonumentation of certain corners in Township 51 North, Range 8 East, New Mexico Principal Meridian, Colorado, were accepted on January 19, 2016.

The plat and field notes of the dependent resurvey and survey in Township 34 North, Range 4 West, South of the Ute Line, New Mexico Principal Meridian, Colorado, were accepted on February 11, 2016.

The plat, in 2 sheets, and field notes of the dependent resurvey and survey in Township 34 North, Range 5 West, South of the Ute Line, New Mexico Principal Meridian, Colorado, were accepted on February 11, 2016.

The plat and field notes of the dependent resurvey survey and survey in Township 36 North, Range 11 East, New Mexico Principal Meridian, Colorado, were accepted on March 9, 2016.

The plat, in 2 sheets, incorporating the field notes of the dependent resurvey and survey of Fractional Township 36 North, Range 12 East, New Mexico Principal Meridian, Colorado, was accepted on March 9, 2016.

Randy Bloom,

Chief Cadastral Surveyor for Colorado.

[FR Doc. 2016–07875 Filed 4–5–16; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–20461; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before February 20, 2016, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by April 21, 2016.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before February 20, 2016. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

DISTRICT OF COLUMBIA

District of Columbia

Jost-Kuhn House, 1354 Madison St. NW., Washington, 16000127

GEORGIA

Elbert County

Bowman Commercial Historic District, Public Square on GA 17, Bowman, 16000128

GUAM

Guam County

Chaqui'an Massacre Site, Chalan Emsley, Yigo, 16000129

IOWA

Muscatine County

Beers and St. John Company Coach Inn, 1193 Highway 6, West Liberty, 16000130

KANSAS

Douglas County

First United Methodist Church of Oregon—California Trail Segment, 867 US 40 Hwy., Lawrence, 16000132

Leavenworth County

Abernathy Furniture Company Factory (Boundary Increase), 100 N. 2nd St., Leavenworth, 16000131

Sedgwick County

Ash—Grove Historic District on East Douglas Avenue, 2100–2330 E. Douglas Ave. (evens); 114 & 117 N. Madison Ave., 111 N.

Sedgwick County

Spruce St.; 115–117 N. Grove St., Wichita, 16000135

Grandview Terrace Apartments, (Residential Resources of Wichita, Sedgwick County, Kansas 1870–1957 MPS), 1736–1748 N. Hillside, Wichita, 16000134

Wabaunsee County

Eskridge Bandstand, Eskridge Cty Park, bet. 4th, 5th, Main & Pine Sts., Eskridge, 16000133

MAINE

Androscoggin County

Danville Junction Grange #65, 15 Grange St., Auburn (Danville), 16000138

Excelsior Grange #5, 446 Harris Hill Rd., Poland, 16000137

Kennebec County

Starling Grange #156 (former), 2769 Main St. (ME 17), Fayette, 16000136

MASSACHUSETTS

Hampden County

St John's Congregational Church & Parsonage—Parish for Working Girls, 69 Hancock St., Springfield, 16000140

Norfolk County

Union Station, West St., Walpole, 16000139

MONTANA

Fergus County

Stafford's Grocery, 201 Main St., Winifred, 16000141

Gallatin County

Elkhorn Ranch Historic District, 33133 Gallatin Rd., Gallatin Gateway, 16000142

NEW HAMPSHIRE

Carroll County

Green Pastures, Address Restricted, Sandwich, 16000145

Hillsborough County

Francestown Town Hall and Academy and Town Common Historic District, 2 New Boston Rd., Francestown, 16000143

Rockingham County

Centennial Hall, 105 Post Rd., North Hampton, 16000144

SOUTH CAROLINA

Anderson County

Ginn, B.J. House, 106 Webb St., Anderson, 16000146

WASHINGTON

King County

Cambridge Apartments, 903 Union St., Seattle, 16000148

Yakima County

First Baptist Church, 515 East Yakima Ave., Yakima, 16000147

WISCONSIN

Marathon County

Manson, Charles L. and Dorothy, House, 1224 Highland Park Blvd., Wausau, 16000149

Authority: 60.13 of 36 CFR part 60.

Dated: February 25, 2016.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2016–07820 Filed 4–5–16; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–20657; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before March 12, 2016, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by April 21, 2016.

ADDRESSES: Comments may be sent via U.S. Postal Service to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before March 12, 2016. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

CALIFORNIA

Tulare County

Bearpaw High Sierra Camp, Sequoia National Park, Three Rivers, 16000192

DISTRICT OF COLUMBIA

District of Columbia

Kalorama Park and Archeological District, 1875 Columbia Rd. NW., Washington, 16000193

Southern Railway Building, 1500 K St. NW., Washington, 16000194

GEORGIA

Fulton County

Capitol View Historic District, Roughly bounded by Hartford Pl., Fairbanks St., Perkerson Park, Sylvan Rd., and Division Pl., Atlanta, 16000195

ILLINOIS

Du Page County

Big Woods School, 3033 N. Eola Rd., Aurora, 16000197

Lawrence County

Bridge at Thirteenth Street, 13th St. between Clark and Johnson Sts., St. Francisville, 16000198

IOWA

Cerro Gordo County

Rock Crest—Rock Glen Historic District (Boundary Increase), 431 First St. SE., 11, 15, 21 Rock Glen, 507, 511, 525, 541 E. State St., 22, 28, 110, 120, 204, South Carolina Ave., Mason City, 16000196

MARYLAND

Wicomico County

United States Post Office, 129 East Main St., Salisbury, 16000199

MICHIGAN

Kalamazoo County

Brown, Eric and Margaret Ann (Davis), House, 2806 Taliesin, Kalamazoo, 16000200

NEW YORK

Greene County

Stanton Hill Cemetery, County Route 50, Hannacroix (Town of New Baltimore), 16000201

St. Lawrence County

Ogdensburg Harbor Lighthouse, 2 Jackson St., Ogdensburg, 16000202

PENNSYLVANIA

Dauphin County

Hotel Lykens, 600 Main St., Lykens, 16000203

Israel Building, 601 Main St., Lykens, 16000204

VIRGINIA

Fauquier County

Broad Run—Little Georgetown Rural Historic District, Roughly bounded by The Plains, Bull Run Mountains, John Marshall Hwy., Bust Head Rd., and Hopewell Rd., Broad Run, 16000205

WISCONSIN

La Crosse County

La Crosse Armory, 2219 South Ave., La Crosse, 16000206

WYOMING

Sheridan County

Robinson—Smith House, 520 South Brooks St., Sheridan, 16000207

Authority: 60.13 of 36 CFR part 60.

Dated: March 18, 2016.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2016–07821 Filed 4–5–16; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA 104000]

Notice of Availability of the Proposed Notice of Sale for Western Gulf of Mexico Planning Area Outer Continental Shelf Oil and Gas Lease Sale 248

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability of the Proposed Notice of Sale for Western Planning Area Lease Sale 248.

SUMMARY: BOEM announces the availability of the Proposed Notice of Sale (NOS) for the proposed Western Planning Area (WPA) Outer Continental Shelf (OCS) Oil and Gas Lease Sale 248 (WPA Sale 248). This Notice is published pursuant to 30 CFR 556.29(c) as a matter of information to the public. With regard to oil and gas leasing on the OCS, the Secretary of the Interior, pursuant to section 19 of the OCS Lands Act, provides affected States the opportunity to review the Proposed NOS. The Proposed NOS sets forth the proposed terms and conditions of the sale, including minimum bids, royalty rates, and rental rates.

DATES: Affected States may comment on the size, timing, and location of proposed WPA Sale 248 within 60 days following their receipt of the Proposed NOS. The Final NOS will be published in the **Federal Register** at least 30 days prior to the date of bid opening. Bid opening currently is scheduled for August 24, 2016.

SUPPLEMENTARY INFORMATION: The Proposed NOS for WPA Sale 248 and Proposed NOS Package containing information essential to potential bidders may be obtained from the Public Information Unit, Gulf of Mexico Region, Bureau of Ocean Energy Management, 1201 Elmwood Park Boulevard, New Orleans, Louisiana 70123–2394. Telephone: (504) 736–2519. The Proposed NOS and Proposed NOS Package also are available on BOEM's Web site at *http://www.boem.gov/Sale-248/.*

Agency Contact: David Diamond, Chief, Leasing Division, *david.diamond@boem.gov.*

Dated: March 28, 2016.

Abigail Ross Hopper,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2016–07917 Filed 4–5–16; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Meeting of the Compact Council for the National Crime Prevention and Privacy Compact

AGENCY: Federal Bureau of Investigation, DOJ.

ACTION: Meeting notice.

SUMMARY: The purpose of this notice is to announce a meeting of the National Crime Prevention and Privacy Compact Council (Council) created by the National Crime Prevention and Privacy Compact Act of 1998 (Compact). Thus far, the Federal Government and 30 states are parties to the Compact which governs the exchange of criminal history records for licensing, employment, and similar purposes. The Compact also provides a legal framework for the establishment of a cooperative federal-state system to exchange such records.

The United States Attorney General appointed 15 persons from state and federal agencies to serve on the Council. The Council will prescribe system rules and procedures for the effective and proper operation of the Interstate Identification Index system for noncriminal justice purposes.

Matters for discussion are expected to include:

(1) Noncriminal Justice Rap Back Audit Plan
(2) Proposed Changes to the National Fingerprint File Qualifications Requirements
(3) 2014 Survey of State Criminal History Information Systems

The meeting will be open to the public on a first-come, first-seated basis. Any member of the public wishing to file a written statement with the Council or wishing to address this session of the Council should notify the Federal Bureau Of Investigation (FBI) Compact Officer, Mr. Gary S. Barron at (304) 625–2803, at least 24 hours prior to the start of the session. The notification should contain the individual's name and corporate designation, consumer affiliation, or government designation, along with a short statement describing the topic to be addressed and the time needed for the presentation. Individuals will ordinarily be allowed up to 15 minutes to present a topic.

DATES: *Dates and Times:* The Council will meet in open session from 9 a.m. until 5 p.m., on May 11–12, 2016.

ADDRESSES: The meeting will take place at the Westin Convention Center, 1000 Penn Avenue, Pittsburgh, Pennsylvania, telephone 412–560–6353.

FOR FURTHER INFORMATION CONTACT: Inquiries may be addressed to Mr. Gary S. Barron, FBI Compact Officer, Module D3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306, telephone (304) 625–2803, facsimile (304) 625–2868.

Dated: March 29, 2016.

Gary S. Barron,

FBI Compact Officer, Criminal Justice Information Services Division, Federal Bureau of Investigation.

[FR Doc. 2016–07869 Filed 4–5–16; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; National Medical Support Notice—Part B

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration sponsored information collection request (ICR) titled, "National Medical Support Notice—Part B," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 6, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201603-1210-004* or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the National Medical Support Notice—Part B information collection. Employee Retirement Income Security Act (ERISA) section 609(a), 29 U.S.C. 1169(a), and regulations 29 CFR 2590.609–2 establish a National Medical Support Notice to provide group health benefits coverage pursuant to Qualified Medical Child Support Orders. Part B, Medical Support Notice to Plan Administrator, is a notice from an employer to a benefits plan administrator to implement coverage of children under ERISA covered group health plans.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0113.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on November 23, 2015 (80 FR 72990).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0113. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: National Medical Support Notice—Part B.

OMB Control Number: 1210–0113.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 492,000.

Total Estimated Number of Responses: 8,700,000.

Total Estimated Annual Time Burden: 727,000 hours.

Total Estimated Annual Other Costs Burden: $4,700,000.

Dated: March 31, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–07886 Filed 4–5–16; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, "Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 6, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201603-1205-003* or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended information collection. Trade Act of 1974 section 221(a), as amended by the Trade and Globalization Adjustment Assistance Act of 2009 (19 U.S.C. 2271), authorizes the Secretary of Labor and the Governor of each State to accept petitions for certification of eligibility to apply for adjustment assistance. Versions of Form ETA–9042, Petition for Trade Adjustment Assistance and Alternative Trade Adjustment Assistance, establish a format that may be used for filing such petitions. DOL regulations regarding petitions for worker adjustment assistance may be found at 29 CFR part 90. Forms ETA–8562a, ETA–8562 a–1, ETA–8562 b, ETA–9118, ETA–9043a, and ETA–9043b are all undertaken in accordance with of the Trade Act sections 222, 223, and 249. The Secretary uses this information to certify whether groups of workers are eligible to apply for worker trade adjustment assistance.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0342.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 17, 2015 (80 FR 78768).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0342. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Petition Requirements and Investigative Data Collection: Trade Act of 1974, as Amended.

OMB Control Number: 1205–0342.

Affected Public: Individuals or Households; State, Local, and Tribal Governments; and Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 6,785.

Total Estimated Number of Responses: 7,439.

Total Estimated Annual Time Burden: 15,483 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 31, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–07885 Filed 4–5–16; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Application for Prevailing Wage Determination

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, "Application for Prevailing Wage Determination," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 6, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201603-1205-002* or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Application for Prevailing Wage Determination, Form ETA–9141, information collection. The information collected via Form ETA–9141 is the basis for the Secretary's determination of the wage an employer must pay in order protect against an adverse effect on U.S. workers' wages by the employment of a foreign worker. The Immigration and Nationality Act authorizes this information collection. *See* 8 U.S.C. 1153(b)(3); 1182(a)(5)(A); 1182(m), (n), (t); and 1184(c).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0508.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on December 10, 2015 (80 FR 76711).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0508. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Application for Prevailing Wage Determination.

OMB Control Number: 1205–0508.

Affected Public: Private Sector—businesses or other for profits.

Total Estimated Number of Respondents: 520,452.

Total Estimated Number of Responses: 1,002,592.

Total Estimated Annual Time Burden: 448.381 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: March 31, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–07887 Filed 4–5–16; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Wage and Hour Division

Agency Information Collection Activities; Comment Extension, Establishing Paid Sick Leave for Federal Contractors

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice.

SUMMARY: This document extends the period for filing comments on the Paperwork Reduction Act and Information Collections ONLY, related to Establishing Paid Sick Leave for Federal Contractors. RIN 1235–AA13, until April 25, 2016. The Notice of Proposed Rulemaking (NPRM), and associated Information Collections were published in the **Federal Register** on February 25, 2016 (81 FR 9592). The affected agency OMB control numbers include: OMB Control Number 1235–0018, Records to be kept by Employers-Fair Labor Standards Act; OMB Control Number 1235–0021, Employment Information Form, and a proposed new collection identified under 1235–0NEW. The Department of Labor (Department) is taking this action in order to provide interested parties additional time to submit comments on the Paperwork Reduction Act and current Information Collections affected by this Rulemaking and the proposed new Information Collection.

DATES: The agency must receive comments on or before April 25, 2016. The period for public comments on the Paperwork Reduction Act and Information Collections, which was set to close on April 12, 2016, will be extended to April 25, 2016. Comments must be received by 11:59 p.m. on April 25, 2016. This notice does not extend the comment period on the NPRM; comments on the NPRM must still be submitted no later than April 12, 2016.

ADDRESSES: You may submit comments identified by Control Number 1235–AA13, by either one of the following methods:

Email: WHDPRAComments@dol.gov;

Mail, Hand Delivery, Courier: Robert Waterman, Compliance Specialist, Division of Regulations, Legislation, and Interpretation, Wage and Hour, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW., Washington, DC 20210.

Comments on the Paperwork Reduction Act and Information Collections affected by this Rulemaking can also continue to be submitted through Regulations.gov, but only through April 12, 2016.

Instructions: Please submit one copy of your comments by only one method. All submissions received must include the agency name and RIN 1235–AA13 or Control Numbers identified above for this information collection. Because we continue to experience delays in receiving mail in the Washington, DC area, commenters are strongly encouraged to transmit their comments electronically via email or to submit them by mail early. Comments, including any personal information provided, become a matter of public record. They will also be summarized and/or included in the request for OMB approval of the information collection request. For additional information on submitting comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Robert Waterman, Compliance Specialist, Division of Regulations, Legislation and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3510, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Copies of the NPRM may be obtained in alternative formats (large print, braille, audio tape, or disc) upon request by calling (202) 693–0023. TTY/TDD callers may dial toll-free (877) 889–5627 to obtain information or request materials in alternative formats.

Questions of interpretation or enforcement of regulations issued by this agency or referenced in this document may be directed to Amy DeBisschop, Director, Government Contracts Branch at (202) 693–0064.

SUPPLEMENTARY INFORMATION:

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95). 44 U.S.C. 3056(c)(2)(A). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Wage and Hour Division is soliciting comments concerning its analysis that the Department's proposed rule, published on February 25, 2016 at 81 FR 9592, if finalized as proposed, would create a slight paperwork burden associated with ICR 1235–0021 but would not create a paperwork burden on the regulated community of the information collection provisions contained in ICR 1235–0018. Additionally, the Department seeks comments on its analysis that this NPRM, if finalized as proposed, would create a new paperwork burden on the regulated community as described in the new information collection provisions contained in ICR 1235–0NEW. While much of the information provided to OMB in support of the information collection request appears in the preamble, interested parties may obtain a copy of the full supporting statements for ICR 1235–0018, ICR 1235–0021, and ICR 1235–0NEW by sending a written request to the email address or mail address shown in the **ADDRESSES** section at the beginning of this notice or by calling the telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Mary Ziegler,

Assistant Administrator for Policy, Wage and Hour Division.

[FR Doc. 2016–07889 Filed 4–5–16; 8:45 am]

BILLING CODE 4510–27–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0006]

Operator Licensing Examination Standards for Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; additional changes and reopen comment period.

SUMMARY: On February 5, 2016, the U.S. Nuclear Regulatory Commission (NRC) published draft NUREG–1021, Revision 11, "Operator Licensing Examination Standards for Power Reactors" for public comment. The public comment period was originally scheduled to close on March 21, 2016. On March 3, 2016, the comment period was extended to April 5, 2016. On March 18, 2016, the NRC posted three updated sections of Examination Standards (ES) in NUREG–1021 that reflect three additional changes that the NRC proposes to incorporate into Revision 11. The public comment period closed on April 5, 2016. The NRC has decided to reopen the public comment period to allow more time for members of the public to develop and submit comments on Revision 11.

DATES: The extended public comment period that ended on April 5, 2016 has been reopened for comments requested in the document published on March 3, 2016 (81 FR 11302), including comments on the additional sections of NUREG–1021 posted on March 18, 2016. Comments should be filed no later than May 6, 2016. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0006. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Maurin Scheetz, telephone: 301–415–2758; email: *Maurin.Scheetz@nrc.gov;* or Timothy Kolb, telephone: 301–415–0783; email: *Timothy.Kolb@nrc.gov*. Both are staff of the Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0006 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0006.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The draft NUREG is available in ADAMS under Accession No. ML16028A409. The updated sections are available in ADAMS under Accession Nos. ML16077A223, ML16077A225, and ML16077A227 for ES–205, ES–501, and ES–502, respectively.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0006 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

On February 5, 2016 (81 FR 6301), the NRC published draft NUREG–1021, Revision 11, "Operator Licensing Examination Standards for Power Reactors" for public comment. The comment period was extended on March 3, 2016 (81 FR 11302). The extended public comment period closed on April 5, 2016. The NRC has decided to reopen the public comment period until May 6, 2016 because three additional changes are proposed for incorporation into the NUREG: (1) Reducing the number of times per year the NRC offers the Generic Fundamentals Examination; (2) eliminating the informal review process; and (3) extending the post-exam comment period. These changes are reflected in updated sections ES–205, Procedures for Administering the Generic Fundamentals Examination Program; ES–501, Initial Post Examination Activities; and ES–502, Denials of Applications. These sections are available for review in the supporting documents section of Docket ID NRC–2016–0006. Specifically, starting in 2017, the NRC proposes to reduce the number of times per year that it offers the Generic Fundamentals Examination from four times per year to two times per year. The NRC proposes to discontinue the informal review process, the practice of performing informal staff reviews of proposed license denials at the request of an applicant. Applicants whose license applications are denied will retain hearing rights under Title 10 of the *Code of Federal Regulations* 2.103(b)(2). Finally, the NRC proposes to extend the post exam comment period to allow the NRC and the facility licensee sufficient time to consider all post exam comments for both the written examination and the operating test. These changes are currently before the Commission for vote as part of the Project AIM re-baselining effort (SECY–16–0009) (ADAMS Accession No. ML16028A189). The NRC presented these changes to the nuclear industry at the Nuclear Energy Institute's National Operator Licensing Workshop on February 9, 2016 and during a panel session at the NRC's Regulatory Information Conference on March 9, 2016. Furthermore, a public meeting was held on March 31, 2016 in Rockville, Maryland, to discuss the scope of these additional changes.

Dated at Rockville, Maryland, this 31 day of March, 2016.

For the Nuclear Regulatory Commission.

Maurin Scheetz,

Acting Chief, Operator Licensing and Training Branch, Division of Inspection and Regional Support, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–07907 Filed 4–5–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

Virgil C. Summer Nuclear Station, Units 2 and 3; South Carolina Electric and Gas; Reconciliation of Tier 1 Valve Differences

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption from certain Tier 1 information in the generic design control document (DCD) and issuing License Amendment No. 31 to combined licenses (COL), NPF–93 and NPF–94. The COLs were issued to South Carolina Electric and Gas (SCE&G) and South Carolina Public Service Authority (Santee Cooper) (the licensee), for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3 located in Fairfield County, South Carolina. The granting of the exemption allows the changes to Tier 1 information and promotes consistency with the VCSNS updated final safety analysis report (UFSAR) Tier 2 information. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: April 6, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Billy Gleaves, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5848; email: *Bill.Gleaves@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from Section III.B of appendix D, "Design Certification Rule for the AP1000," to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment No. 31 to COLs, NPF–93 and NPF–94, to the licensee. The exemption is required by paragraph A.4 of Section VIII, "Processes for Changes and Departures," appendix D to 10 CFR part 52 for changes to generic DCD Tier 1 information. Specifically, with the requested amendment, the licensee sought to make changes to Tier 1 tables and promote consistency with the UFSAR Tier 2 information. The request for the amendment and exemption were submitted by letter dated February 7, 2013 (ADAMS Accession No. ML13042A005), and supplemented by letters dated July 19, 2013, November 21, 2013, February 6, 2014, February 20, 2014, May 12, 2014, September 22, 2014, and November 19, 2014 (ADAMS Accession Nos. ML13205A148, ML13329A723, ML14041A095, ML14052A379, ML14133A488, ML14266A014, and ML14323A333, respectively).

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and 10 CFR 52.63(b)(1) of appendix D to 10 CFR part

52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML15204A476.

Identical exemption documents (except as needed to reflect the unique unit numbers and license numbers) were issued to the licensee for VCSNS Units 2 and 3 (COLs NPF–93 and NPF–94). These documents can be found in ADAMS under Accession Nos. ML15204A442 and ML15204A445, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–93 and NPF–94 are available in ADAMS under Accession Nos. ML15204A416 and ML15204A426, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption issued to VCSNS Units 2 and 3. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC in order to grant the exemption:

1. In a letter dated February 7, 2013, and supplemented by the letters dated July 19, 2013, November 21, 2013, February 6, 2014, February 20, 2014, May 12, 2014, September 22, 2014, and November 19, 2014, South Carolina Electric & Gas Company (licensee) requested from the Nuclear Regulatory Commission (NRC/Commission) an exemption to allow departures from Tier 1 information in the certified design control document (DCD) incorporated by reference in title 10 of the *Code of Federal Regulations* (10 CFR), part 52, appendix D, "Design Certification Rule for the AP1000 Design," as part of license amendment request (LAR) 13–04, "Reconciliation of Tier 1 Valve Differences."

For the reasons set forth in Section 3.1 of the NRC staff's safety evaluation, which can be found in ADAMS under Accession No. ML15204A476, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1 and COL Appendix C, Tables 2.1.2–1. 2.2.1–1, 2.2.2–1, 2.2.3–1, 2.2.3–3, 2.2.5–1, 2.3.2–1, 2.3.2–3, and 2.3.6–1, as described in the licensee's request dated February 7, 2013, and supplemented by the letters dated July 19, 2013, November 21, 2013, February 6, 2014, February 20, 2014, May 12, 2014, September 22, 2014, and November 19, 2014. This exemption is related to, and necessary for the granting of License Amendment No. 31, which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's safety evaluation (ADAMS Accession No. ML15204A476), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated February 7, 2013, as supplemented, the licensee requested that the NRC amend the COLs for VCSNS Units 2 and 3, COLs NPF–93 and NPF–94. The licensee request and supplements are listed in Section I, above.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on October 29, 2013 (78 FR 64541). No comments were received during the 60-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on September 3, 2015. The exemption and amendment were issued to the licensee on September 3, 2015 as part of a package of documents (ADAMS Accession No. ML15204A391).

Dated at Rockville, Maryland, this 30th day of March 2016.

For the Nuclear Regulatory Commission.

William (Billy) Gleaves,

Senior Project Manager, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–07904 Filed 4–5–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–117 and CP2016–148; Order No. 3209]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of First-Class Package Service Contract 50 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add First-Class Package Service Contract 50 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–117 and CP2016–148 to consider the Request pertaining to the proposed First-Class Package Service Contract 50 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–117 and CP2016–148 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than April 8, 2016.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–07876 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add First-Class Package Service Contract 50 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 31, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–143; Order No. 3210]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning notice to enter into an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On March 31, 2016, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–143 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Natalie R. Ward to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–143 for consideration of the matters raised by the Postal Service's Notice.
2. Pursuant to 39 U.S.C. 505, Natalie R. Ward is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).
3. Comments are due no later than April 8, 2016.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–07877 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, March 31, 2016 (Notice).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–116 and CP2016–147; Order No. 3208]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of First-Class Package Service Contract 49 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add First-Class Package Service Contract 49 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–116 and CP2016–147 to consider the Request pertaining to the proposed First-Class Package Service Contract 49 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–116 and CP2016–147 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than April 8, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–07871 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add First-Class Package Service Contract 49 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 31, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–114 and CP2016–145; Order No. 3206]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 204 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 204 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–114 and CP2016–145 to consider the Request pertaining to the proposed Priority Mail Contract 204 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–114 and CP2016–145 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than April 8, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–07863 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add Priority Mail Contract 204 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 31, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–115 and CP2016–146; Order No. 3207]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 205 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's

Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30–.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 205 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–115 and CP2016–146 to consider the Request pertaining to the proposed Priority Mail Contract 205 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–115 and CP2016–146 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than April 8, 2016.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–07870 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Request of the United States Postal Service to Add Priority Mail Contract 205 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, March 31, 2016 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–142; Order No. 3205]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning notice to enter into an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On March 31, 2016, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–142 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Katalin K. Clendenin to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–142 for consideration of the matters raised by the Postal Service's Notice.
2. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).
3. Comments are due no later than April 8, 2016.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–07862 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, March 31, 2016 (Notice).

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2016–144; Order No. 3211]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning notice to enter into an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 8, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On March 31, 2016, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–144 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 8, 2016. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–144 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than April 8, 2016.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2016–07878 Filed 4–5–16; 8:45 am]

BILLING CODE 7710–FW–P

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[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, March 31, 2016 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77489; File No. SR–ISE–2016–08]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing of Proposed Rule Change Related to Market Wide Risk Protection

March 31, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on March 17, 2016, the International Securities Exchange, LLC (the "Exchange" or "ISE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to introduce new activity based order protections as described in more detail below. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to introduce new risk protections for orders designed to aid members in their risk management by supplementing current price reasonability checks with activity based order protections.[3] In particular, the Exchange proposes to introduce two activity based risk protections that will be mandatory for all members: (1) The "Order Entry Rate Protection," which protects members against *entering* orders at a rate that exceeds predefined thresholds,[4] and (2) the "Order Execution Rate Protection," which protects members against *executing* orders at a rate that exceeds their predefined risk settings. Both of these risk protections are detailed in Proposed Rule 714(d), "Market Wide Risk Protection."[5] The Exchange will announce the implementation date of the Market Wide Risk Protection in a circular to be distributed to members prior to implementation.

Pursuant to the proposed Market Wide Risk Protection rule, the Exchange's trading system (the "System") will maintain one or more counting programs on behalf of each member that will count the number of orders entered, and the number of contracts traded on ISE or, if chosen by the member,[6] across both ISE and ISE's affiliate, ISE Gemini, LLC ("ISE Gemini"), which shares a trading system with ISE. Members can use multiple counting programs to separate risk protections for different groups established within the member.[7] The counting programs will maintain separate counts, over rolling time periods specified by the member for each count, of: (1) The total number of orders entered in the regular order book; (2) the total number of orders entered in the complex order book with only options legs; (3) the total number of orders entered in the complex order book with both stock and options legs; (4) the total number of contracts traded in regular orders; and (5) the total number of contracts traded in complex orders with only options legs.[8]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange provides members with limit order price protections designed to prevent erroneous executions by rejecting orders priced too far through the market. *See* Rule 714(b)(2).

[4] The Exchange will determine when to initiate the Order Entry Rate Protection pre-open to allow members time to load their orders without inadvertently triggering the protection. The precise time will be established by the Exchange and communicated to members via circular prior to implementation.

[5] The term "Market Wide Risk Protection" includes both the "Order Entry Rate Protection" and the "Order Execution Rate Protection."

[6] Members will have the option to set different risk parameters for their trading activity on each exchange, or set risk parameters that apply to their trading across both ISE and ISE Gemini, if desired.

[7] The Exchange will explain how members can go about setting up risk protections for different groups

Members will have discretion to establish the applicable time period for each of the counts maintained under the Market Wide Risk Protection, provided that the selected period must be within minimum and maximum parameters established by the Exchange and announced via circular.[9] While the Market Wide Risk Protection is mandatory for all members, the Exchange is not proposing to establish minimum or maximum values for the order entry and execution parameters described in (1) through (5) above. The Exchange believes that this approach will give members the flexibility needed to appropriately tailor the Market Wide Risk Protection to their respective risk management needs. In this regard, the Exchange notes that each member is in the best position to determine risk settings appropriate for their firm based on the member's trading activity and business needs. In the interest of maintaining a fair and orderly market, however, the Exchange will establish default values for the applicable time period and order entry and execution parameters in a circular to be distributed to members. Default values established by the Exchange will apply only to members that do not submit their own parameters for the Market Wide Risk Protection.

The Exchange proposes to use separate counts for regular orders, complex options orders, and complex orders with a stock component as members may want to have different risk settings for these instruments. In order to fully protect members, however, if the Market Wide Risk Protection is triggered based on any count, the triggered action will be taken across the entire market. In particular, if the Market Wide Risk Protection is triggered, action will be taken with respect to all products traded in both simple and complex instruments, and across ISE or, if applicable, ISE and ISE Gemini. Contracts executed on the agency and contra-side of a two-sided crossing order will be counted separately for the Order Execution Rate Protection. In addition, the contract execution count for complex orders will be the sum of the number of contracts executed with respect to each leg. Complex instruments that contain a stock component will not be included as part of the complex order execution count as the Order Execution Rate Protection is based exclusively on options contracts executed, and therefore does not apply to orders that have both stock and options components.[10]

The System will trigger the Market Wide Risk Protection when the counting program has determined that the member has either (1) entered during the specified time period a number of orders exceeding its designated allowable order rate, or (2) executed during the specified time period a number of contracts exceeding its designated allowable contract execution rate. In particular, after a member enters an order, or a member's order is executed, the System will look back over the specified time period to determine whether the member has exceeded the threshold that it has set for the total number of orders entered or the total number of contracts traded, as applicable. If the member's threshold has been exceeded in either simple or complex instruments, the Market Wide Risk Protection will be triggered and the System will automatically reject all subsequent incoming orders entered by the member on ISE or, if applicable, across both ISE and ISE Gemini.[11] In addition, if the member has opted in to this functionality, the System will automatically cancel all of the member's existing orders. The Market Wide Risk Protection will remain engaged until the member manually (*e.g.*, via email) notifies the Exchange to enable the acceptance of new orders; however, the System will still allow members to interact with existing orders entered before the protection was triggered, including sending cancel order messages and receiving trade executions for those orders.

The Exchange believes that the proposed Market Wide Risk Protection will assist members in better managing their risk when trading on the [sic] ISE. In particular, the proposed rule change provides functionality that allows members to set risk management thresholds for the number of orders entered or contracts executed on the Exchange during a specified period. This is similar to how other options exchanges have implemented activity-based risk management protections,[12] and the Exchange believes this functionality will likewise be beneficial for ISE members.

The examples below illustrate how the Market Wide Risk Protection would work both for order entry and order execution protections:

Example 1, Order Entry Rate Protection:

Broker Dealer 1 ("BD1") designates an allowable order rate of 499 orders/1 second in simple instruments, 299 orders/1 second in complex options orders, and 199 orders/1 second in complex orders with a stock component.

@0 milliseconds, BD1 enters 200 regular orders. (Regular order total: 200 orders)
@150 milliseconds, BD1 enters 50 complex options orders. (Complex options order total: 50 orders)
@250 milliseconds, BD1 enters 100 complex orders with a stock component. (Complex order with stock total: 100 orders)
@450 milliseconds, BD1 enters 250 regular orders. (Regular order total: 450 orders)
@950 milliseconds, BD1 enters 50 regular orders. (Regular order total: 500 orders)

Market Wide Risk Protection is triggered on ISE, and, if applicable, ISE Gemini[13] due to exceeding 499 regular orders in 1 second. All subsequent orders in both simple and complex

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(*e.g.*, business units) in a circular issued to members.

[8] The member's allowable order rate for the Order Entry Rate Protection is comprised of the parameters defined in (1) to (3), while the allowable contract execution rate for the Order Execution Rate Protection is comprised of the parameters defined in (4) and (5). As explained below, the Exchange is not including a complex execution count for complex orders with a stock component as the execution counts maintained by the Order Execution Rate Protection are based solely on options contracts traded. *See* note 9 supra [sic] and accompanying text.

[9] The Exchange anticipates that the minimum and maximum values for the applicable time period will be initially set at one second and a full trading day, respectively.

[10] Stock-option orders contain both an option component(s) executed in contracts and a stock component executed in shares. The Exchange does not believe that these two components can be combined in a way that provides a meaningful measure of risk exposure for members, and has therefore determined not to provide the Order Execution Rate Protection for complex orders that contain a stock component.

[11] Members that set different risk parameters for ISE and ISE Gemini will only have their orders rejected on the exchange whose threshold was exceeded.

[12] *See* Securities Exchange Act Release Nos. 74118 (January 22, 2015), 80 FR 4605 (January 28, 2015) (Notice); 74496 (March 13, 2015), 80 FR 14421 (March 19, 2015) (Approval) (SR–MIAX–2015–03).

[13] Members that share risk settings across both ISE and ISE Gemini will have the Market Wide Risk Protection triggered on both markets.

instruments are rejected, and if BD1 has opted in to this functionality, all existing orders are cancelled. BD1 must contact Market Operations to resume trading.

Example 2, Order Execution Rate Protection:

BD1 designates an allowable execution rate of 15,000 contracts/2 seconds in simple instruments and 10,000 contracts/2 seconds in complex options orders.

@0 milliseconds, BD1 receives executions for 5,000 contracts from regular orders. (Regular execution total: 5,000 contracts)
@500 milliseconds, BD1 receives an execution for 2,500 contracts from a complex options order. (Complex execution total: 2,500 contracts)
@600 milliseconds, BD1 receives executions for 10,000 contracts from regular orders. (Regular execution total: 15,000 contracts)
@650 milliseconds, BD1 receives an execution for 1,500 contracts from a stock-option order. (Complex execution total: 2,500 contracts)[14]
@850 milliseconds, BD1 receives an execution for 3,000 contracts from a complex options order. (Complex execution total: 5,500 contracts)
@1150 milliseconds, BD1 receives an execution for 3,000 contracts from a complex options order. (Complex execution total: 8,500 contracts)
@1700 milliseconds, BD1 receives an execution for 2,000 contracts from a complex options order. (Complex execution total: 10,500 contracts)

Market Wide Risk Protection is triggered on ISE, and, if applicable, ISE Gemini[15] due to exceeding 10,000 contracts in 2 seconds for complex options orders. All subsequent orders in both simple and complex instruments are rejected, and if BD1 has opted in to this functionality, all existing orders are cancelled. BD1 must contact Market Operations to resume trading.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[16] Specifically, the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] because it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would assist with the maintenance of a fair and orderly market by establishing new activity based risk protections for orders. The Exchange currently offers a risk protection mechanism for market maker quotes that removes the member's quotes if a specified number of curtailment events occur during a set time period ("Market Wide Speed Bump").[18] The Exchange believes that this Market Wide Speed Bump functionality has been successful in reducing market maker risk and now proposes to adopt risk protections for orders that would allow other members to properly manage their exposure to excessive risk. In particular, the proposed rule change would implement two new risk protections based on the rate of order entry and order execution, respectively. The Exchange believes that both of these new protections, which together encompass the proposed Market Wide Risk Protection, would enable members to better manage their risk when trading options on the Exchange by limiting the member's risk exposure when systems or other issues result in orders being entered or executed at a rate that exceeds predefined thresholds. In today's market the Exchange believes that robust risk management is becoming increasingly more important for all members. The proposed rule change would provide an additional layer of risk protection for market participants that trade on the Exchange.

The proposed Market Wide Risk Protection is similar to risk management functionality provided by other options exchanges, including, for example, the MIAX Options Exchange ("MIAX"), which recently received Commission approval for its "Risk Protection Monitor" for orders.[19] In particular, the Market Wide Risk Protection is designed to reduce risk associated with system errors or market events that may cause members to send a large number of orders, or receive multiple, automatic executions, before they can adjust their exposure in the market. Without adequate risk management tools, such as those proposed in this filing, members could reduce the amount of order flow and liquidity that they provide. Such actions may undermine the quality of the markets available to customers and other market participants. Accordingly, the proposed rule change is designed to encourage members to submit additional order flow and liquidity to the Exchange, thereby removing impediments to and perfect [sic] the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest. In addition, providing members with more tools for managing risk will facilitate transactions in securities because, as noted above, the members will have more confidence that protections are in place that reduce the risks from potential system errors and market events. As a result, the new functionality has the potential to promote just and equitable principles of trade.

The Exchange also believes that it is consistent with the protection of investors and the public interest to offer the Market Wide Risk Protection to members across both ISE and ISE Gemini as this will permit members to more effectively manage their risk simultaneously on both markets if desired. The Exchange already offers cross market risk protections for market makers [sic] quotes,[20] and is now proposing to similarly offer a cross market risk protection for orders in order to reduce the risk that members face when entering orders on multiple exchanges. The Exchange notes that issues that would trigger the Market Wide Risk Protection are not normally confined to a member's activity on a single exchange. Accordingly, the Exchange believes that offering the Market Wide Risk Protection on a cross-market basis would help members to more effectively manage their risk when trading on multiple markets, and reduce disruptive trading events to the benefit of all members and investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[21] the Exchange does not believe that the proposed rule change would impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed Market Wide Risk Protection is similar to risk protections already available on other options exchanges,[22] and is designed to be a competitive offering that would mitigate the risk associated with trading on the Exchange. Market makers already benefit from Market Wide Speed Bump functionality available for quotes. The proposed change would extend new risk protections to orders so that additional market participants can benefit from risk mitigating functionality. Like the Exchange's Market Wide Speed Bump, the proposed rule change would also be offered cross-market to members that want to be protected from inadvertent exposure to excessive risk when trading on both ISE and ISE Gemini. Permitting this functionality to be cross-market will not have any impact on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In addition, the proposed functionality would be mandatory for all members, and would be made available on an equal and non-discriminatory basis. As such, the Exchange does not believe that the proposed rule change would impose any unnecessary burden on competition.

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[14] Complex orders with a stock component are not included in the order execution count.

[15] Members that share risk settings across both ISE and ISE Gemini will have the Market Wide Risk Protection triggered on both markets.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Rule 804(g)(2).

[19] *See* supra note 10 [sic].

[20] *See* Securities Exchange Act Release Nos. 71759 (March 20, 2014), 79 FR 16850 (March 26, 2014) ("Notice"); 73147 (September 19, 2014), 79 FR 57639 (September 25, 2014) (Approval) (SR–ISE–2014–09).

[21] 15 U.S.C. 78f(b)(8).

[22] *See* supra notes 10 [sic] and 19.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the publication date of this notice or within such longer period (1) as the Commission may designate up to 45 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (2) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve or disapprove such proposed rule change; or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISE–2016–08 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2016–08. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2016–08 and should be submitted on or before April 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07834 Filed 4–5–16; 8:45 am]

BILLING CODE 8011–01–P

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[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32063; 812–14537]

Advisors Asset Management, Inc. and AAM ETF Trust; Notice of Application

March 31, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

SUMMARY: *Summary of Application:* Applicants request an order that would permit (a) series of certain open-end management investment companies to issue shares ("Shares") redeemable in large aggregations only ("Creation Units"); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; and (e) certain registered management investment companies and unit investment trusts ("UITs") outside of the same group of investment companies as the series to acquire Shares.

Applicants: Advisors Asset Management Inc. (the "Initial Adviser") and AAM ETF Trust (the "Trust").

DATES: *Filing Dates:* The application was filed on August 20, 2015, and amended on January 13, 2016.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 25, 2016, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the

Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549; Applicants: Scott I. Coyler, Advisors Asset Management, Inc., 18925 Base Camp Road, Suite 203, Monument, Colorado 80132.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 551–6876, or Mary Kay Frech, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Trust is a business trust organized under the laws of the Commonwealth of Massachusetts and intends to register under the Act as an open-end management investment company with multiple series. Each series for which the Trust seeks the requested order will operate as an exchange traded fund ("ETF").

2. The Initial Adviser is registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act") and will be the investment adviser to the Funds (defined below). Any other Adviser (defined below) also will be registered as an investment adviser under the Advisers Act. The Adviser may enter into sub-advisory agreements with one or more investment advisers to act as sub-advisers to particular Funds (each, a "Sub-Adviser"). Any Sub-Adviser will either be registered under the Advisers Act or will not be required to register thereunder.

3. The Trust will enter into a distribution agreement with one or more distributors. Each distributor for a Fund will be a broker-dealer ("Broker") registered under the Securities Exchange Act of 1934 ("Exchange Act") and will act as distributor and principal underwriter ("Distributor") for one or more of the Funds. No Distributor will be affiliated with any national securities exchange, as defined in section 2(a)(26) of the Act ("Exchange"). The Distributor for each Fund will comply with the terms and conditions of the requested order.

4. Applicants request that the order apply to the initial series of the Trust described in the application ("Initial Fund") and any additional series of the Trust, and any other open-end management investment company or series thereof, that may be created in the future ("Future Funds" and together with the Initial Fund, "Funds"), each of which will operate as an ETF and will track a specified index comprised of domestic or foreign equity and/or fixed income securities, or a blend of domestic and/or foreign equity and fixed income securities (each, an "Underlying Index"). Any Fund will (a) be advised by the Initial Adviser or an entity controlling, controlled by, or under common control with the Initial Adviser (each such entity and any successor thereto, an "Adviser")[1] and (b) comply with the terms and conditions of the application.[2]

5. Each Fund will hold certain securities, currencies, other assets, and other investment positions ("Portfolio Holdings") selected to correspond generally to the performance of its Underlying Index. The Underlying Indexes will be comprised of equity and/or fixed income securities issued by one or more of the following categories of issuers: (i) Domestic issuers and (ii) non-domestic issuers meeting the requirements for trading in U.S. markets. Other Funds will be based on Underlying Indexes that will be comprised of foreign and domestic, or solely foreign, equity and/or fixed income securities ("Foreign Funds").

6. Applicants represent that each Fund will invest at least 80% of its assets (excluding securities lending collateral) in the component securities of its respective Underlying Index ("Component Securities") and TBA Transactions,[3] and in the case of Foreign Funds, Component Securities and Depositary Receipts[4] representing Component Securities. Each Fund may also invest up to 20% of its assets in a broad variety of other instruments including, but not limited to, repurchase agreements, reverse repurchase agreements, government securities, cash and cash equivalents, commodities, options, futures contracts, currency futures contracts, options on futures contracts, swaps, options on swaps, forward contracts or other derivatives or financial instruments (including, but not limited to, credit-linked notes, commodity-linked notes, forward commitment transactions, foreign currency forwards, indexed and inverse floating rate securities, floating and variable rate instruments, convertible instruments, preferred stocks, rights and warrants), real estate investment trusts, shares of other ETFs, UITs and exchange-traded notes, and shares of money market mutual funds or other investment companies or pooled investment vehicles, foreign currency, mortgage-backed securities, asset-backed securities, municipal debt securities, when-issued securities and delayed delivery transactions, including securities and other instruments not included in its Underlying Index but which the Fund's Adviser or any Sub-Adviser believes will help the Fund track its Underlying Index. A Fund may also engage in short sales in accordance with its investment objective.

7. The Trust may offer Funds that seek to track Underlying Indexes constructed using 130/30 investment strategies ("130/30 Funds") or other long/short investment strategies ("Long/Short Funds"). Each Long/Short Fund will establish (i) exposures equal to approximately 100% of the long positions specified by the Long/Short Index[5] and (ii) exposures equal to approximately 100% of the short

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[1] For the purposes of the requested order, a "successor" is limited to an entity or entities that result from reorganization into another jurisdiction or a change in the type of business organization.

[2] All existing entities that intend to rely on the requested order have been named as applicants. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the order. A Fund of Funds (as defined below) may rely on the order only to invest in Underlying Funds (as defined below) and not in any other registered investment company.

[3] A "to-be-announced transaction" or "TBA Transaction" is a method of trading mortgage-backed securities. In a TBA Transaction, the buyer and seller agree upon general trade parameters such as agency, settlement date, par amount and price. The actual pools delivered generally are determined two days prior to settlement date.

[4] Depositary receipts representing foreign securities ("Depositary Receipts") include American Depositary Receipts and Global Depositary Receipts. The Funds may invest in Depositary Receipts representing foreign securities in which they seek to invest. Depositary Receipts are typically issued by a financial institution (a "depositary bank") and evidence ownership interests in a security or a pool of securities that have been deposited with the depositary bank. A Fund will not invest in any Depositary Receipts that the Adviser or any Sub-Adviser deems to be illiquid or for which pricing information is not readily available. No affiliated person of a Fund, the Adviser or any Sub-Adviser will serve as the depositary bank for any Depositary Receipts held by a Fund, except a depositary bank that is deemed to be affiliated solely because a Fund owns greater than 5% of the outstanding voting securities of such depositary bank.

[5] Underlying Indexes that include both long and short positions in securities are referred to as "Long/Short Indexes."

positions specified by the Long/Short Index. Each 130/30 Fund will include strategies that: (i) Establish long positions in securities so that total long exposure represents approximately 130% of a Fund's net assets; and (ii) simultaneously establish short positions in other securities so that total short exposure represents approximately 30% of such Fund's net assets. Each Business Day (as defined below), for each Long/Short Fund and 130/30 Fund, the Adviser will provide full portfolio transparency on the Fund's publicly available Web site ("Web site") by making available the Fund's Portfolio Holdings before the commencement of trading of Shares on the Listing Exchange (defined below).[6] The information provided on the Web site will be formatted to be reader-friendly.

8. A Fund will utilize either a replication or representative sampling strategy to track its Underlying Index. A Fund using a replication strategy will invest in the Component Securities of its Underlying Index in the same approximate proportions as in such Underlying Index. A Fund using a representative sampling strategy will hold some, but not necessarily all of the Component Securities of its Underlying Index. Applicants state that a Fund using a representative sampling strategy will not be expected to track the performance of its Underlying Index with the same degree of accuracy as would an investment vehicle that invested in every Component Security of the Underlying Index with the same weighting as the Underlying Index. Applicants expect that each Fund will have an annual tracking error relative to the performance of its Underlying Index of less than 5%.

9. Each Fund will be entitled to use its Underlying Index pursuant to either a licensing agreement with the entity that compiles, creates, sponsors or maintains the Underlying Index (each, an "Index Provider") or a sub-licensing arrangement with the Adviser, which will have a licensing agreement with such Index Provider.[7] A "Self-Indexing Fund" is a Fund for which an affiliated person, as defined in section 2(a)(3) of the Act ("Affiliated Person"), or an affiliated person of an Affiliated Person ("Second-Tier Affiliate"), of the Trust or a Fund, of the Adviser, of any Sub-Adviser to or promoter of a Fund, or of the Distributor (each, an "Affiliated Index Provider")[8] will serve as the Index Provider. In the case of Self-Indexing Funds, an Affiliated Index Provider will create a proprietary, rules-based methodology to create Underlying Indexes (each an "Affiliated Index").[9] Except with respect to the Self-Indexing Funds, no Index Provider is or will be an Affiliated Person, or a Second-Tier Affiliate, of the Trust or a Fund, of the Adviser, of any Sub-Adviser to or promoter of a Fund, or of the Distributor.

10. Applicants recognize that Self-Indexing Funds could raise concerns regarding the ability of the Affiliated Index Provider to manipulate the Underlying Index to the benefit or detriment of the Self-Indexing Fund. Applicants further recognize the potential for conflicts that may arise with respect to the personal trading activity of personnel of the Affiliated Index Provider who have knowledge of changes to an Underlying Index prior to the time that information is publicly disseminated.

11. Applicants propose that each Self-Indexing Fund will post on its Web site, on each day the Fund is open, including any day when it satisfies redemption requests as required by section 22(e) of the Act (a "Business Day"), before commencement of trading of Shares on the Listing Exchange, the identities and quantities of the Portfolio Holdings that will form the basis for the Fund's calculation of its NAV at the end of the Business Day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will also provide an additional mechanism for addressing any such potential conflicts of interest.

12. In addition, applicants do not believe the potential for conflicts of interest raised by the Adviser's use of the Underlying Indexes in connection with the management of the Self Indexing Funds and the Affiliated Accounts will be substantially different from the potential conflicts presented by an adviser managing two or more registered funds. Both the Act and the Advisers Act contain various protections to address conflicts of interest where an adviser is managing two or more registered funds and these protections will also help address these conflicts with respect to the Self-Indexing Funds.[10]

13. The Adviser and any Sub-Adviser have adopted or will adopt, pursuant to Rule 206(4)–7 under the Advisers Act, written policies and procedures designed to prevent violations of the Advisers Act and the rules thereunder. These include policies and procedures designed to minimize potential conflicts of interest among the Self-Indexing Funds and the Affiliated Accounts, such as cross trading policies, as well as those designed to ensure the equitable allocation of portfolio transactions and brokerage commissions. In addition, the Initial Adviser has adopted or will adopt policies and procedures as required under section 204A of the Advisers Act, which are reasonably designed in light of the nature of its business to prevent the misuse, in violation of the Advisers Act or the Exchange Act or the rules thereunder, of material non-public information by the Initial Adviser or an associated person ("Inside Information Policy"). Any other Adviser or Sub-Adviser will be required to adopt and maintain a similar Inside Information Policy. In accordance with the Code of Ethics[11] and Inside Information Policy of the Adviser and any Sub-Adviser, personnel of those entities with knowledge about the composition of the Portfolio Deposit[12]

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[6] Under accounting procedures followed by each Fund, trades made on the prior Business Day ("T") will be booked and reflected in NAV on the current Business Day (T+1). Accordingly, the Funds will be able to disclose at the beginning of the Business Day the portfolio that will form the basis for the NAV calculation at the end of the Business Day.

[7] The licenses for the Self-Indexing Funds will specifically state that the Affiliated Index Provider (as defined below), or in case of a sub-licensing agreement, the Adviser, must provide the use of the Affiliated Indexes (as defined below) and related intellectual property at no cost to the applicable Trust and the Self-Indexing Funds.

[8] In the event that an Adviser or Sub-Adviser serves as the Affiliated Index Provider for a Self-Indexing Fund, the terms "Affiliated Index Provider" or "Index Provider," with respect to that Self-Indexing Fund, will refer to the employees of the applicable Adviser or Sub-Adviser that are responsible for creating, compiling and maintaining the relevant Underlying Index.

[9] The Affiliated Indexes may be made available to registered investment companies, as well as separately managed accounts of institutional investors and privately offered funds that are not deemed to be "investment companies" in reliance on section 3(c)(1) or 3(c)(7) of the Act for which the Adviser acts as adviser or subadviser ("Affiliated Accounts") as well as other such registered investment companies, separately managed accounts and privately offered funds for which it does not act either as adviser or subadviser ("Unaffiliated Accounts"). The Affiliated Accounts and the Unaffiliated Accounts, like the Funds, would seek to track the performance of one or more Underlying Index(es) by investing in the constituents of such Underlying Indexes or a representative sample of such constituents of the Underlying Index. Consistent with the relief requested from section 17(a), the Affiliated Accounts will not engage in Creation Unit transactions with a Fund.

[10] *See, e.g.,* Rule 17j–1 under the Act and section 204A under the Advisers Act and Rules 204A–1 and 206(4)–7 under the Advisers Act.

[11] The Adviser has also adopted or will adopt a code of ethics pursuant to Rule 17j–1 under the Act and Rule 204A–1 under the Advisers Act, which contains provisions reasonably necessary to prevent Access Persons (as defined in Rule 17j–1) from engaging in any conduct prohibited in Rule 17j–1 ("Code of Ethics").

[12] The instruments and cash that the purchaser is required to deliver in exchange for the Creation

Continued

will be prohibited from disclosing such information to any other person, except as authorized in the course of their employment, until such information is made public. In addition, an Index Provider will not provide any information relating to changes to an Underlying Index's methodology for the inclusion of Component Securities, the inclusion or exclusion of specific Component Securities, or methodology for the calculation or the return of Component Securities, in advance of a public announcement of such changes by the Index Provider. The Adviser will also include under Item 10.C of Part 2 of its Form ADV a discussion of its relationship to any Affiliated Index Provider and any material conflicts of interest resulting therefrom, regardless of whether the Affiliated Index Provider is a type of affiliate specified in Item 10.

14. To the extent the Self-Indexing Funds transact with an Affiliated Person of the Adviser or Sub-Adviser, such transactions will comply with the Act, the rules thereunder and the terms and conditions of the requested order. In this regard, each Self-Indexing Fund's board of directors or trustees ("Board") will periodically review the Self-Indexing Fund's use of an Affiliated Index Provider. Subject to the approval of the Self-Indexing Fund's Board, the Adviser, Affiliated Persons of the Adviser ("Adviser Affiliates") and Affiliated Persons of any Sub-Adviser ("Sub-Adviser Affiliates") may be authorized to provide custody, fund accounting and administration and transfer agency services to the Self-Indexing Funds. Any services provided by the Adviser, Adviser Affiliates, Sub-Adviser and Sub-Adviser Affiliates will be performed in accordance with the provisions of the Act, the rules under the Act and any relevant guidelines from the staff of the Commission.

15. The Shares of each Fund will be purchased and redeemed in Creation Units and generally on an in-kind basis. Except where the purchase or redemption will include cash under the limited circumstances specified below, purchasers will be required to purchase Creation Units by making an in-kind deposit of specified instruments ("Deposit Instruments"), and shareholders redeeming their Shares will receive an in-kind transfer of specified instruments ("Redemption Instruments").[13] On any given Business Day, the names and quantities of the instruments that constitute the Deposit Instruments and the names and quantities of the instruments that constitute the Redemption Instruments will be identical, unless the Fund is Rebalancing (as defined below). In addition, the Deposit Instruments and the Redemption Instruments will each correspond pro rata to the positions in the Fund's portfolio (including cash positions)[14] except: (a) In the case of bonds, for minor differences when it is impossible to break up bonds beyond certain minimum sizes needed for transfer and settlement; (b) for minor differences when rounding is necessary to eliminate fractional shares or lots that are not tradeable round lots;[15] (c) TBA Transactions, short positions, derivatives and other positions that cannot be transferred in kind[16] will be excluded from the Deposit Instruments and the Redemption Instruments;[17] (d) to the extent the Fund determines, on a given Business Day, to use a representative sampling of the Fund's portfolio;[18] or (e) for temporary periods, to effect changes in the Fund's portfolio as a result of the rebalancing of its Underlying Index (any such change, a "Rebalancing"). If there is a difference between the NAV attributable to a Creation Unit and the aggregate market value of the Deposit Instruments or Redemption Instruments exchanged for the Creation Unit, the party conveying instruments with the lower value will also pay to the other an amount in cash equal to that difference (the "Cash Amount").

16. Purchases and redemptions of Creation Units may be made in whole or in part on a cash basis, rather than in kind, solely under the following circumstances: (a) To the extent there is a Cash Amount; (b) if, on a given Business Day, the Fund announces before the open of trading that all purchases, all redemptions or all purchases and redemptions on that day will be made entirely in cash; (c) if, upon receiving a purchase or redemption order from an Authorized Participant, the Fund determines to require the purchase or redemption, as applicable, to be made entirely in cash;[19] (d) if, on a given Business Day, the Fund requires all Authorized Participants purchasing or redeeming Shares on that day to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are not eligible for transfer through either the NSCC or DTC (defined below); or (ii) in the case of Foreign Funds holding non-U.S. investments, such instruments are not eligible for trading due to local trading restrictions, local restrictions on securities transfers or other similar circumstances; or (e) if the Fund permits an Authorized Participant to deposit or receive (as applicable) cash in lieu of some or all of the Deposit Instruments or Redemption Instruments, respectively, solely because: (i) Such instruments are, in the case of the purchase of a Creation Unit, not available in sufficient quantity; (ii) such instruments are not eligible for trading by an Authorized Participant or the investor on whose behalf the Authorized Participant is acting; or (iii) a holder of Shares of a Foreign Fund holding non-U.S. investments would be subject to unfavorable income tax treatment if the holder receives redemption proceeds in kind.[20]

17. Creation Units will consist of specified large aggregations of Shares (*e.g.*, at least 25,000 Shares) as determined by the Adviser, and it is

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Units it is purchasing are referred to as the "Portfolio Deposit."

[13] The Funds must comply with the federal securities laws in accepting Deposit Instruments and satisfying redemptions with Redemption Instruments, including that the Deposit Instruments and Redemption Instruments are sold in transactions that would be exempt from registration under the Securities Act of 1933 ("Securities Act"). In accepting Deposit Instruments and satisfying redemptions with Redemption Instruments that are restricted securities eligible for resale pursuant to rule 144A under the Securities Act, the Funds will comply with the conditions of rule 144A.

[14] The portfolio used for this purpose will be the same portfolio used to calculate the Fund's NAV for the Business Day.

[15] A tradeable round lot for a security will be the standard unit of trading in that particular type of security in its primary market.

[16] This includes instruments that can be transferred in kind only with the consent of the original counterparty to the extent the Fund does not intend to seek such consents.

[17] Because these instruments will be excluded from the Deposit Instruments and the Redemption Instruments, their value will be reflected in the determination of the Cash Amount (as defined below).

[18] A Fund may only use sampling for this purpose if the sample: (i) Is designed to generate performance that is highly correlated to the performance of the Fund's portfolio; (ii) consists entirely of instruments that are already included in the Fund's portfolio; and (iii) is the same for all Authorized Participants (as defined below) on a given Business Day.

[19] In determining whether a particular Fund will sell or redeem Creation Units entirely on a cash or in-kind basis (whether for a given day or a given order), the key consideration will be the benefit that would accrue to the Fund and its investors. For instance, in bond transactions, the Adviser may be able to obtain better execution than Share purchasers because of the Adviser's size, experience and potentially stronger relationships in the fixed income markets. Purchases of Creation Units either on an all cash basis or in-kind are expected to be neutral to the Funds from a tax perspective. In contrast, cash redemptions typically require selling portfolio holdings, which may result in adverse tax consequences for the remaining Fund shareholders that would not occur with an in-kind redemption. As a result, tax consideration may warrant in-kind redemptions.

[20] A "custom order" is any purchase or redemption of Shares made in whole or in part on a cash basis in reliance on clause (e)(i) or (e)(ii).

expected that the initial price of a Creation Unit will fall in the range of $1 million to $10 million. All orders to purchase Creation Units must be placed with the Distributor by or through an "Authorized Participant" which is either (1) a "Participating Party," *i.e.*, a Broker or other participant in the Continuous Net Settlement System of the NSCC, a clearing agency registered with the Commission, or (2) a participant in The Depository Trust Company ("DTC") ("DTC Participant"), which, in either case, has signed a participant agreement with the Distributor. The Distributor will be responsible for transmitting the orders to the Funds and will furnish to those placing such orders confirmation that the orders have been accepted, but applicants state that the Distributor may reject any order which is not submitted in proper form.

18. Each Business Day, before the open of trading on the Exchange on which Shares are primarily listed ("Listing Exchange"), each Fund will cause to be published through the NSCC the names and quantities of the instruments comprising the Deposit Instruments and the Redemption Instruments, as well as the estimated Cash Amount (if any), for that day. The list of Deposit Instruments and Redemption Instruments will apply until a new list is announced on the following Business Day, and there will be no intra-day changes to the list except to correct errors in the published list. Each Listing Exchange will disseminate, every 15 seconds during regular Exchange trading hours, through the facilities of the Consolidated Tape Association, an amount for each Fund stated on a per individual Share basis representing the sum of (i) the estimated Cash Amount and (ii) the current value of the Deposit Instruments.

19. Transaction expenses, including operational processing and brokerage costs, will be incurred by a Fund when investors purchase or redeem Creation Units in-kind and such costs have the potential to dilute the interests of the Fund's existing shareholders. Each Fund will impose purchase or redemption transaction fees ("Transaction Fees") in connection with effecting such purchases or redemptions of Creation Units. In all cases, such Transaction Fees will be limited in accordance with requirements of the Commission applicable to management investment companies offering redeemable securities. Since the Transaction Fees are intended to defray the transaction expenses as well as to prevent possible shareholder dilution resulting from the purchase or redemption of Creation Units, the Transaction Fees will be borne only by such purchasers or redeemers.[21] The Distributor will be responsible for delivering the Fund's prospectus to those persons acquiring Shares in Creation Units and for maintaining records of both the orders placed with it and the confirmations of acceptance furnished by it. In addition, the Distributor will maintain a record of the instructions given to the applicable Fund to implement the delivery of its Shares.

20. Shares of each Fund will be listed and traded individually on an Exchange. It is expected that one or more member firms of an Exchange will be designated to act as a market maker (each, a "Market Maker") and maintain a market for Shares trading on the Exchange. Prices of Shares trading on an Exchange will be based on the current bid/offer market. Transactions involving the sale of Shares on an Exchange will be subject to customary brokerage commissions and charges.

21. Applicants expect that purchasers of Creation Units will include institutional investors and arbitrageurs. Market Makers, acting in their roles to provide a fair and orderly secondary market for the Shares, may from time to time find it appropriate to purchase or redeem Creation Units. Applicants expect that secondary market purchasers of Shares will include both institutional and retail investors.[22] The price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

22. Shares will not be individually redeemable, and owners of Shares may acquire those Shares from the Fund, or tender such Shares for redemption to the Fund, in Creation Units only. To redeem, an investor must accumulate enough Shares to constitute a Creation Unit. Redemption requests must be placed through an Authorized Participant. A redeeming investor will pay a Transaction Fee, calculated in the same manner as a Transaction Fee payable in connection with purchases of Creation Units.

23. Neither the Trust nor any Fund will be advertised or marketed or otherwise held out as a traditional open-end investment company or a "mutual fund." Instead, each such Fund will be marketed as an "ETF." All marketing materials that describe the features or method of obtaining, buying or selling Creation Units, or Shares traded on an Exchange, or refer to redeemability, will prominently disclose that Shares are not individually redeemable and will disclose that the owners of Shares may acquire those Shares from the Fund or tender such Shares for redemption to the Fund in Creation Units only. The Funds will provide copies of their annual and semi-annual shareholder reports to DTC Participants for distribution to beneficial owners of Shares.

Applicants' Legal Analysis

1. Applicants request an order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c–1 under the Act, under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provisions of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

Sections 5(a)(1) and 2(a)(32) of the Act

3. Section 5(a)(1) of the Act defines an "open-end company" as a management investment company that is offering for

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[21] Where a Fund permits an in-kind purchaser to substitute cash-in-lieu of depositing one or more of the requisite Deposit Instruments, the purchaser may be assessed a higher Transaction Fee to cover the cost of purchasing such Deposit Instruments.

[22] Shares will be registered in book-entry form only. DTC or its nominee will be the record or registered owner of all outstanding Shares. Beneficial ownership of Shares will be shown on the records of DTC or the DTC Participants.

sale or has outstanding any redeemable security of which it is the issuer. Section 2(a)(32) of the Act defines a redeemable security as any security, other than short-term paper, under the terms of which the owner, upon its presentation to the issuer, is entitled to receive approximately a proportionate share of the issuer's current net assets, or the cash equivalent. Because Shares will not be individually redeemable, applicants request an order that would permit the Funds to register as open-end management investment companies and issue Shares that are redeemable in Creation Units only. Applicants state that investors may purchase Shares in Creation Units and redeem Creation Units from each Fund. Applicants further state that because Creation Units may always be purchased and redeemed at NAV, the price of Shares on the secondary market should not vary materially from NAV.

Section 22(d) of the Act and Rule 22c–1 Under the Act

4. Section 22(d) of the Act, among other things, prohibits a dealer from selling a redeemable security that is currently being offered to the public by or through an underwriter, except at a current public offering price described in the prospectus. Rule 22c–1 under the Act generally requires that a dealer selling, redeeming or repurchasing a redeemable security do so only at a price based on its NAV. Applicants state that secondary market trading in Shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Thus, purchases and sales of Shares in the secondary market will not comply with section 22(d) of the Act and rule 22c–1 under the Act. Applicants request an exemption under section 6(c) from these provisions.

5. Applicants assert that the concerns sought to be addressed by section 22(d) of the Act and rule 22c–1 under the Act with respect to pricing are equally satisfied by the proposed method of pricing Shares. Applicants maintain that while there is little legislative history regarding section 22(d), its provisions, as well as those of rule 22c–1, appear to have been designed to (a) prevent dilution caused by certain riskless-trading schemes by principal underwriters and contract dealers, (b) prevent unjust discrimination or preferential treatment among buyers, and (c) ensure an orderly distribution of investment company shares by eliminating price competition from dealers offering shares at less than the published sales price and repurchasing shares at more than the published redemption price.

6. Applicants believe that none of these purposes will be thwarted by permitting Shares to trade in the secondary market at negotiated prices. Applicants state that (a) secondary market trading in Shares does not involve a Fund as a party and will not result in dilution of an investment in Shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces, such as supply and demand. Therefore, applicants assert that secondary market transactions in Shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants contend that the price at which Shares trade will be disciplined by arbitrage opportunities created by the option continually to purchase or redeem Shares in Creation Units, which should help prevent Shares from trading at a material discount or premium in relation to their NAV.

Section 22(e)

7. Section 22(e) of the Act generally prohibits a registered investment company from suspending the right of redemption or postponing the date of payment of redemption proceeds for more than seven days after the tender of a security for redemption. Applicants state that settlement of redemptions for Foreign Funds will be contingent not only on the settlement cycle of the United States market, but also on current delivery cycles in local markets for underlying foreign securities held by a Foreign Fund. Applicants state that the delivery cycles currently practicable for transferring Redemption Instruments to redeeming investors, coupled with local market holiday schedules, may require a delivery process of up to fifteen (15) calendar days.[23] Accordingly, with respect to Foreign Funds only, applicants hereby request relief under section 6(c) from the requirement imposed by section 22(e) to allow Foreign Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption.[24]

8. Applicants believe that Congress adopted section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds. Applicants propose that allowing redemption payments for Creation Units of a Foreign Fund to be made within fifteen calendar days would not be inconsistent with the spirit and intent of section 22(e). Applicants suggest that a redemption payment occurring within fifteen calendar days following a redemption request would adequately afford investor protection.

9. Applicants are not seeking relief from section 22(e) with respect to Foreign Funds that do not effect creations and redemptions of Creation Units in-kind.

Section 12(d)(1)

10. Section 12(d)(1)(A) of the Act prohibits a registered investment company from acquiring securities of an investment company if such securities represent more than 3% of the total outstanding voting stock of the acquired company, more than 5% of the total assets of the acquiring company, or, together with the securities of any other investment companies, more than 10% of the total assets of the acquiring company. Section 12(d)(1)(B) of the Act prohibits a registered open-end investment company, its principal underwriter and any other broker-dealer from knowingly selling the investment company's shares to another investment company if the sale will cause the acquiring company to own more than 3% of the acquired company's voting stock, or if the sale will cause more than 10% of the acquired company's voting stock to be owned by investment companies generally.

11. Applicants request an exemption to permit registered management investment companies and UITs that are not advised or sponsored by the Adviser, and not part of the same "group of investment companies," as defined in section 12(d)(1)(G)(ii) of the Act as the Underlying Funds (such management investment companies are referred to as "Investing Management Companies," such UITs are referred to as "Investing Trusts," and Investing Management Companies and Investing Trusts are collectively referred to as "Funds of Funds")[25], to acquire Underlying Fund Shares beyond the limits of section 12(d)(1)(A) of the Act; and the Underlying Funds, and any principal underwriter for the Underlying Funds, and/or any Broker registered under the Exchange Act, to sell Underlying Fund Shares to Funds of Funds beyond the limits of section

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[23] Applicants state that certain countries in which a Fund may invest have historically had settlement periods of up to fifteen (15) calendar days.

[24] Applicants acknowledge that no relief obtained from the requirements of section 22(e) will affect any obligations applicants may otherwise have under rule 15c6–1 under the Exchange Act requiring that most securities transactions be settled within three business days of the trade date.

[25] Funds of Funds do not include the Underlying Funds.

12(d)(1)(B) of the Act. The "Underlying Funds" are (a) the Funds and (b) any registered open-end management investment company or any series thereof that is advised by an Adviser and that, pursuant to a separate order of the Commission, in general terms, operates as an ETF that utilizes active management investment strategies. Shares of an Underlying Fund are referred to as "Underlying Fund Shares."

12. Each Investing Management Company will be advised by an investment adviser within the meaning of section 2(a)(20)(A) of the Act (the "Fund of Funds Adviser") and may be sub-advised by investment advisers within the meaning of section 2(a)(20)(B) of the Act (each, a "Fund of Funds Sub-Adviser"). Any investment adviser to an Investing Management Company will be registered under the Advisers Act. Each Investing Trust will be sponsored by a sponsor ("Sponsor").

13. Applicants submit that the proposed conditions to the requested relief adequately address the concerns underlying the limits in sections 12(d)(1)(A) and (B), which include concerns about undue influence by a fund of funds over underlying funds, excessive layering of fees and overly complex fund structures. Applicants believe that the requested exemption is consistent with the public interest and the protection of investors.

14. Applicants believe that neither a Fund of Funds nor a Fund of Funds Affiliate would be able to exert undue influence over an Underlying Fund.[26] To limit the control that a Fund of Funds may have over an Underlying Fund, applicants propose a condition prohibiting a Fund of Funds Adviser or Sponsor, any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act that is advised or sponsored by a Fund of Funds Adviser or Sponsor, or any person controlling, controlled by, or under common control with a Fund of Funds Adviser or Sponsor ("Fund of Funds Advisory Group") from controlling (individually or in the aggregate) an Underlying Fund within the meaning of section 2(a)(9) of the Act. The same prohibition would apply to any Fund of Funds Sub-Adviser, any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser, and any investment company or issuer that would be an investment company but for sections 3(c)(1) or 3(c)(7) of the Act (or portion of such investment company or issuer) advised or sponsored by the Fund of Funds Sub-Adviser or any person controlling, controlled by or under common control with the Fund of Funds Sub-Adviser ("Fund of Funds Sub-Advisory Group").

15. Applicants propose other conditions to limit the potential for undue influence over the Underlying Funds, including that no Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to an Underlying Fund) will cause an Underlying Fund to purchase a security in an offering of securities during the existence of an underwriting or selling syndicate of which a principal underwriter is an Underwriting Affiliate ("Affiliated Underwriting"). An "Underwriting Affiliate" is a principal underwriter in any underwriting or selling syndicate that is an officer, director, member of an advisory board, Fund of Funds Adviser, Fund of Funds Sub-Adviser, employee or Sponsor of the Fund of Funds, or a person of which any such officer, director, member of an advisory board, Fund of Funds Adviser or Fund of Funds Sub-Adviser, employee or Sponsor is an affiliated person (except that any person whose relationship to the Underlying Fund is covered by section 10(f) of the Act is not an Underwriting Affiliate).

16. Applicants do not believe that the proposed arrangement will involve excessive layering of fees. The board of directors or trustees of any Investing Management Company, including a majority of the directors or trustees who are not "interested persons" within the meaning of section 2(a)(19) of the Act ("disinterested directors or trustees"), will find that the advisory fees charged under the contract are based on services provided that will be in addition to, rather than duplicative of, services provided under the advisory contract of any Underlying Fund in which the Investing Management Company may invest. In addition, under condition B.5., a Fund of Funds Adviser, or a Fund of Funds' trustee or Sponsor, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by a Fund under rule 12b-1 under the Act) received from an Underlying Fund by the Fund of Funds Adviser, trustee or Sponsor or an affiliated person of the Fund of Funds Adviser, trustee or Sponsor, other than any advisory fees paid to the Fund of Funds Adviser, trustee or Sponsor or its affiliated person by an Underlying Fund, in connection with the investment by the Fund of Funds in the Underlying Fund. Applicants state that any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.[27]

17. Applicants submit that the proposed arrangement will not create an overly complex fund structure. Applicants note that no Underlying Fund will acquire securities of any investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent permitted by exemptive relief from the Commission permitting the Underlying Fund to purchase shares of other investment companies for short-term cash management purposes. To ensure a Fund of Funds is aware of the terms and conditions of the requested order, the Fund of Funds will enter into an agreement with the Underlying Fund ("FOF Participation Agreement"). The FOF Participation Agreement will include an acknowledgement from the Fund of Funds that it may rely on the order only to invest in the Underlying Funds and not in any other investment company.

18. Applicants also note that an Underlying Fund may choose to reject a direct purchase of Underlying Fund Shares in Creation Units by a Fund of Funds. To the extent that a Fund of Funds purchases Underlying Fund Shares in the secondary market, an Underlying Fund would still retain its ability to reject any initial investment by a Fund of Funds in excess of the limits of section 12(d)(1)(A) by declining to enter into a FOF Participation Agreement with the Fund of Funds.

Sections 17(a)(1) and (2) of the Act

19. Sections 17(a)(1) and (2) of the Act generally prohibit an affiliated person of a registered investment company, or an affiliated person of such a person, from selling any security to or purchasing any security from the company. Section 2(a)(3) of the Act defines "affiliated person" of another person to include (a) any person directly or indirectly

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[26] A "Fund of Funds Affiliate" is a Fund of Funds Adviser, Fund of Funds Sub-Adviser, Sponsor, promoter, and principal underwriter of a Fund of Funds, and any person controlling, controlled by, or under common control with any of those entities. An "Underlying Fund Affiliate" is an investment adviser, promoter, or principal underwriter of an Underlying Fund and any person controlling, controlled by or under common control with any of these entities.

[27] Any references to NASD Conduct Rule 2830 include any successor or replacement FINRA rule to NASD Conduct Rule 2830.

owning, controlling or holding with power to vote 5% or more of the outstanding voting securities of the other person, (b) any person 5% or more of whose outstanding voting securities are directly or indirectly owned, controlled or held with the power to vote by the other person, and (c) any person directly or indirectly controlling, controlled by or under common control with the other person. Section 2(a)(9) of the Act defines "control" as the power to exercise a controlling influence over the management or policies of a company, and provides that a control relationship will be presumed where one person owns more than 25% of a company's voting securities. The Funds may be deemed to be controlled by the Adviser or an entity controlling, controlled by or under common control with the Adviser and hence affiliated persons of each other. In addition, the Funds may be deemed to be under common control with any other registered investment company (or series thereof) advised by an Adviser or an entity controlling, controlled by or under common control with an Adviser (an "Affiliated Fund"). Any investor, including Market Makers, owning 5% or holding in excess of 25% of a Trust or such Funds, may be deemed affiliated persons of that Trust or such Funds. In addition, an investor could own 5% or more, or in excess of 25% of the outstanding shares of one or more Affiliated Funds making that investor a Second-Tier Affiliate of the Funds.

20. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act pursuant to sections 6(c) and 17(b) of the Act to permit persons that are Affiliated Persons of the Funds, or Second-Tier Affiliates of the Funds, solely by virtue of one or more of the following: (a) holding 5% or more, or in excess of 25%, of the outstanding Shares of one or more Funds; (b) an affiliation with a person with an ownership interest described in (a); or (c) holding 5% or more, or more than 25%, of the shares of one or more Affiliated Funds, to effectuate purchases and redemptions "in-kind."

21. Applicants assert that no useful purpose would be served by prohibiting such affiliated persons from making "in-kind" purchases or "in-kind" redemptions of Shares of a Fund in Creation Units. Both the deposit procedures for "in-kind" purchases of Creation Units and the redemption procedures for "in-kind" redemptions of Creation Units will be effected in exactly the same manner for all purchases and redemptions, regardless of size or number. There will be no discrimination between purchasers or redeemers. Deposit Instruments and Redemption Instruments for each Fund will be valued in the identical manner as those Portfolio Holdings currently held by such Fund and the valuation of the Deposit Instruments and Redemption Instruments will be made in an identical manner regardless of the identity of the purchaser or redeemer. Applicants do not believe that "in-kind" purchases and redemptions will result in abusive self-dealing or overreaching, but rather assert that such procedures will be implemented consistently with each Fund's objectives and with the general purposes of the Act. Applicants believe that "in-kind" purchases and redemptions will be made on terms reasonable to applicants and any affiliated persons because they will be valued pursuant to verifiable objective standards. The method of valuing Portfolio Holdings held by a Fund is identical to that used for calculating "in-kind" purchase or redemption values and therefore creates no opportunity for affiliated persons or Second-Tier Affiliates of applicants to effect a transaction detrimental to the other holders of Shares of that Fund. Similarly, applicants submit that, by using the same standards for valuing Portfolio Holdings held by a Fund as are used for calculating "in-kind" redemptions or purchases, the Fund will ensure that its NAV will not be adversely affected by such securities transactions. Applicants also note that the ability to take deposits and make redemptions "in-kind" will help each Fund to track closely its Underlying Index and therefore aid in achieving the Fund's objectives.

22. Applicants also seek relief under sections 6(c) and 17(b) from section 17(a) to permit an Underlying Fund that is an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds to sell its Underlying Fund Shares to and redeem its Underlying Fund Shares from a Fund of Funds, and to engage in the accompanying in-kind transactions with the Fund of Funds.[28] Applicants state that the terms of the transactions are fair and reasonable and do not involve overreaching. Applicants note that any consideration paid by a Fund of Funds for the purchase or redemption of Underlying Fund Shares directly from an Underlying Fund will be based on the NAV of the Underlying Fund.[29] Applicants believe that any proposed transactions directly between the Underlying Funds and Funds of Funds will be consistent with the policies of each Fund of Funds. The purchase of Creation Units by a Fund of Funds directly from an Underlying Fund will be accomplished in accordance with the investment restrictions of any such Fund of Funds and will be consistent with the investment policies set forth in the Fund of Funds' registration statement. Applicants also state that the proposed transactions are consistent with the general purposes of the Act and are appropriate in the public interest.

Applicants' Conditions

Applicants agree that any order of the Commission granting the requested relief will be subject to the following conditions:

A. ETF Relief

1. The requested relief to permit ETF operations will expire on the effective date of any Commission rule under the Act that provides relief permitting the operation of index-based ETFs.

2. As long as a Fund operates in reliance on the requested order, the Shares of such Fund will be listed on an Exchange.

3. Neither the Trust nor any Fund will be advertised or marketed as an open-end investment company or a mutual fund. Any advertising material that describes the purchase or sale of Creation Units or refers to redeemability will prominently disclose that Shares are not individually redeemable and that owners of Shares may acquire those Shares from the Fund and tender those Shares for redemption to a Fund in Creation Units only.

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[28] Although applicants believe that most Funds of Funds will purchase Underlying Fund Shares in the secondary market and will not purchase Creation Units directly from an Underlying Fund, a Fund of Funds might seek to transact in Creation Units directly with an Underlying Fund that is an affiliated person of a Fund of Funds. To the extent that purchases and sales of Underlying Fund Shares occur in the secondary market and not through principal transactions directly between a Fund of Funds and an Underlying Fund, relief from section 17(a) would not be necessary. However, the requested relief would apply to direct sales of Underlying Fund Shares in Creation Units by an Underlying Fund to a Fund of Funds and redemptions of those Underlying Fund Shares. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where an Underlying Fund could be deemed an affiliated person, or an affiliated person of an affiliated person of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

[29] Applicants acknowledge that the receipt of compensation by (a) an affiliated person of a Fund of Funds, or an affiliated person of such person, for the purchase by the Fund of Funds of Shares of an Underlying Fund or (b) an affiliated person of an Underlying Fund, or an affiliated person of such person, for the sale by the Underlying Fund of its Shares to a Fund of Funds, may be prohibited by section 17(e)(1) of the Act. The FOF Participation Agreement also will include this acknowledgment.

4. The Web site, which is and will be publicly accessible at no charge, will contain, on a per Share basis for each Fund, the prior Business Day's NAV and the market closing price or the midpoint of the bid/ask spread at the time of the calculation of such NAV ("Bid/Ask Price"), and a calculation of the premium or discount of the market closing price or Bid/Ask Price against such NAV.

5. Each Self-Indexing Fund, Long/Short Fund and 130/30 Fund will post on the Web site on each Business Day, before commencement of trading of Shares on the Exchange, the Fund's Portfolio Holdings.

6. No Adviser or any Sub-Adviser to a Self-Indexing Fund, directly or indirectly, will cause any Authorized Participant (or any investor on whose behalf an Authorized Participant may transact with the Self-Indexing Fund) to acquire any Deposit Instrument for a Self-Indexing Fund through a transaction in which the Self-Indexing Fund could not engage directly.

B. Fund of Funds Relief

1. The members of a Fund of Funds' Advisory Group will not control (individually or in the aggregate) an Underlying Fund within the meaning of section 2(a)(9) of the Act. The members of a Fund of Funds' Sub-Advisory Group will not control (individually or in the aggregate) an Underlying Fund within the meaning of section 2(a)(9) of the Act. If, as a result of a decrease in the outstanding voting securities of an Underlying Fund, the Fund of Funds' Advisory Group or the Fund of Funds' Sub-Advisory Group, each in the aggregate, becomes a holder of more than 25 percent of the outstanding voting securities of an Underlying Fund, it will vote its Underlying Fund Shares of the Underlying Fund in the same proportion as the vote of all other holders of the Underlying Fund's Shares. This condition does not apply to the Fund of Funds' Sub-Advisory Group with respect to an Underlying Fund for which the Fund of Funds' Sub-Adviser or a person controlling, controlled by or under common control with the Fund of Funds' Sub-Adviser acts as the investment adviser within the meaning of section 2(a)(20)(A) of the Act.

2. No Fund of Funds or Fund of Funds Affiliate will cause any existing or potential investment by the Fund of Funds in an Underlying Fund to influence the terms of any services or transactions between the Fund of Funds or Fund of Funds Affiliate and the Underlying Fund or an Underlying Fund Affiliate.

3. The board of directors or trustees of an Investing Management Company, including a majority of the disinterested directors or trustees, will adopt procedures reasonably designed to ensure that the Fund of Funds Adviser and Fund of Funds Sub-Adviser are conducting the investment program of the Investing Management Company without taking into account any consideration received by the Investing Management Company or a Fund of Funds Affiliate from an Underlying Fund or Underlying Fund Affiliate in connection with any services or transactions.

4. Once an investment by a Fund of Funds in Underlying Fund Shares exceeds the limits in section 12(d)(1)(A)(i) of the Act, the Board of the Underlying Fund, including a majority of the directors or trustees who are not "interested persons" within the meaning of section 2(a)(19) of the Act ("non-interested Board members"), will determine that any consideration paid by the Underlying Fund to the Fund of Funds or a Fund of Funds Affiliate in connection with any services or transactions: (i) is fair and reasonable in relation to the nature and quality of the services and benefits received by the Underlying Fund; (ii) is within the range of consideration that the Underlying Fund would be required to pay to another unaffiliated entity in connection with the same services or transactions; and (iii) does not involve overreaching on the part of any person concerned. This condition does not apply with respect to any services or transactions between an Underlying Fund and its investment adviser(s), or any person controlling, controlled by or under common control with such investment adviser(s).

5. The Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, as applicable, will waive fees otherwise payable to it by the Fund of Funds in an amount at least equal to any compensation (including fees received pursuant to any plan adopted by an Underlying Fund under rule 12b-l under the Act) received from an Underlying Fund by the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, or an affiliated person of the Fund of Funds Adviser, or trustee or Sponsor of the Investing Trust, other than any advisory fees paid to the Fund of Funds Adviser, or trustee or Sponsor of an Investing Trust, or its affiliated person by the Underlying Fund, in connection with the investment by the Fund of Funds in the Underlying Fund. Any Fund of Funds Sub-Adviser will waive fees otherwise payable to the Fund of Funds Sub-Adviser, directly or indirectly, by the Investing Management Company in an amount at least equal to any compensation received from an Underlying Fund by the Fund of Funds Sub-Adviser, or an affiliated person of the Fund of Funds Sub-Adviser, other than any advisory fees paid to the Fund of Funds Sub-Adviser or its affiliated person by the Underlying Fund, in connection with the investment by the Investing Management Company in the Underlying Fund made at the direction of the Fund of Funds Sub-Adviser. In the event that the Fund of Funds Sub-Adviser waives fees, the benefit of the waiver will be passed through to the Investing Management Company.

6. No Fund of Funds or Fund of Funds Affiliate (except to the extent it is acting in its capacity as an investment adviser to an Underlying Fund) will cause an Underlying Fund to purchase a security in any Affiliated Underwriting.

7. The Board of an Underlying Fund, including a majority of the non-interested Board members, will adopt procedures reasonably designed to monitor any purchases of securities by the Underlying Fund in an Affiliated Underwriting, once an investment by a Fund of Funds in the securities of the Underlying Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, including any purchases made directly from an Underwriting Affiliate. The Board of the Underlying Fund will review these purchases periodically, but no less frequently than annually, to determine whether the purchases were influenced by the investment by the Fund of Funds in the Underlying Fund. The Board of the Underlying Fund will consider, among other things: (i) Whether the purchases were consistent with the investment objectives and policies of the Underlying Fund; (ii) how the performance of securities purchased in an Affiliated Underwriting compares to the performance of comparable securities purchased during a comparable period of time in underwritings other than Affiliated Underwritings or to a benchmark such as a comparable market index; and (iii) whether the amount of securities purchased by the Underlying Fund in Affiliated Underwritings and the amount purchased directly from an Underwriting Affiliate have changed significantly from prior years. The Board will take any appropriate actions based on its review, including, if appropriate, the institution of procedures designed to ensure that purchases of securities in Affiliated Underwritings are in the best interest of shareholders of the Underlying Fund.

8. Each Underlying Fund will maintain and preserve permanently in an easily accessible place a written copy of the procedures described in the preceding condition, and any modifications to such procedures, and will maintain and preserve for a period of not less than six years from the end of the fiscal year in which any purchase in an Affiliated Underwriting occurred, the first two years in an easily accessible place, a written record of each purchase of securities in Affiliated Underwritings once an investment by a Fund of Funds in the securities of the Underlying Fund exceeds the limit of section 12(d)(1)(A)(i) of the Act, setting forth from whom the securities were acquired, the identity of the underwriting syndicate's members, the terms of the purchase, and the information or materials upon which the determinations of the Board of the Underlying Fund were made.

9. Before investing in an Underlying Fund in excess of the limit in section 12(d)(1)(A), a Fund of Funds and the Trust will execute a FOF Participation Agreement stating, without limitation, that their respective boards of directors or trustees and their investment advisers, or trustee and Sponsor, as applicable, understand the terms and conditions of the order, and agree to fulfill their responsibilities under the order. At the time of its investment in Underlying Fund Shares in excess of the limit in section 12(d)(1)(A)(i), a Fund of Funds will notify the Underlying Fund of the investment. At such time, the Fund of Funds will also transmit to the Underlying Fund a list of the names of each Fund of Funds Affiliate and Underwriting Affiliate. The Fund of Funds will notify the Underlying Fund of any changes to the list of the names as soon as reasonably practicable after a change occurs. The Underlying Fund and the Fund of Funds will maintain and preserve a copy of the order, the FOF Participation Agreement, and the list with any updated information for the duration of the investment and for a period of not less than six years thereafter, the first two years in an easily accessible place.

10. Before approving any advisory contract under section 15 of the Act, the board of directors or trustees of each Investing Management Company including a majority of the disinterested directors or trustees, will find that the advisory fees charged under such contract are based on services provided that will be in addition to, rather than duplicative of, the services provided under the advisory contract(s) of any Underlying Fund in which the Investing Management Company may invest. These findings and their basis will be fully recorded in the minute books of the appropriate Investing Management Company.

11. Any sales charges and/or service fees charged with respect to shares of a Fund of Funds will not exceed the limits applicable to a fund of funds as set forth in NASD Conduct Rule 2830.

12. No Underlying Fund will acquire securities of an investment company or company relying on section 3(c)(1) or 3(c)(7) of the Act in excess of the limits contained in section 12(d)(1)(A) of the Act, except to the extent the Underlying Fund acquires securities of another investment company pursuant to exemptive relief from the Commission permitting the Underlying Fund to acquire securities of one or more investment companies for short-term cash management purposes.

For the Commission, by the Division of Investment Management, under delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07835 Filed 4–5–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77487; File No. SR–BATS–2015–105]

Self-Regulatory Organizations; BATS Exchange, Inc.; Order Granting Approval of Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3 Thereto, To List and Trade Shares of the Elkhorn S&P GSCI Dynamic Roll Commodity ETF of Elkhorn ETF Trust

March 31, 2016.

I. Introduction

On December 18, 2015, BATS Exchange, Inc. ("Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares ("Shares") of the Elkhorn S&P GSCI Dynamic Roll Commodity ETF ("Fund") of Elkhorn ETF Trust ("Trust") under BATS Rule 14.11(i). The proposed rule change was published for comment in the **Federal Register** on January 4, 2016.[3] On February 17, 2016, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On February 18, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.[6] On February 24, 2016, the Exchange filed Amendment No. 2 to the proposed rule change.[7] On March 22, 2016, the Exchange filed Amendment No. 3 to the proposed rule change.[8] The Commission received no comments on the proposal. This order grants approval of the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76776 (Dec. 28, 2015), 81 FR 120 ("Notice").

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 77159, 81 FR 9041 (Feb. 23, 2016). The Commission designated April 1, 2016 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change. *See id.*

[6] In Amendment No. 1, which amended and replaced the proposed rule change in its entirety, the Exchange clarified the scope of the non-exchange-traded investment companies, futures, and exchange-traded options on futures to be held by the Fund and the Subsidiary. Because Amendment No. 1 to the proposed rule change does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 1 is not subject to notice and comment (Amendment No. 1 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-bats-2015–105/bats2015105–2.pdf*).

[7] In Amendment No. 2, which amended and replaced the proposed rule change, as modified by Amendment No. 1 thereto, in its entirety, the Exchange clarified: (a) That the Fund and the Subsidiary would not invest in leveraged or inverse leveraged securities of investment companies; (b) that the commodity-linked instruments in which the Fund invests will be listed and traded in the U.S. on registered exchanges; (c) that, for surveillance, the Exchange would be able to obtain information regarding trading in the underlying commodity-linked instruments; and (d) the scope of exchange-traded options on futures contracts to be held by the Fund and Subsidiary. Because Amendment No. 2 to the proposed rule change does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 2 is not subject to notice and comment (Amendment No. 2 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-bats-2015–105/bats2015105–1.pdf*).

[8] In Amendment No. 3 to the proposed rule change, the Exchange clarified that: (a) All statements and representations made in the proposal shall constitute continued listing requirements for listing the Shares on the Exchange; (b) the issuer will advise the Exchange of any failure by the Fund to comply with the continued listing requirements; (c) pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements; and (d) if the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. Because Amendment No. 3 does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 3 is not subject to notice and comment (Amendment No. 3 to the proposed rule change is available at: *https://www.sec.gov/comments/sr-bats-2015-105/bats2015105-3.pdf*).

II. Exchange's Description of the Proposed Rule Change

The Exchange proposes to list and trade the Shares of the Fund pursuant to BATS Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange. The Shares will be offered by the Trust, which was established as a Massachusetts business trust on December 12, 2013.[9] Elkhorn Investments, LLC will be the investment adviser ("Adviser") to the Fund. It is currently anticipated that day-to-day portfolio management for the Fund will be provided by the Adviser. However, the Fund and the Adviser may contract with an investment sub-adviser ("Sub-Adviser") to provide day-to-day portfolio management for the Fund. ALPS Distributors, Inc. will be the principal underwriter and distributor of the Fund's Shares. The Fund will contract with unaffiliated third parties to provide administrative, custodial and transfer agency services to the Fund. The Exchange represents the Adviser is not a broker-dealer, but is affiliated with a broker-dealer, and it has implemented a fire wall with respect to its broker-dealer affiliate regarding access to information concerning the composition of, or changes to, the Fund's portfolio.[10]

A. Exchange's Description of the Fund's Investments[11]

According to the Exchange, the Fund's investment objective will be to provide total return which exceeds that of the S&P GSCI Dynamic Roll Index ("Benchmark")[12] consistent with prudent investment management.[13] The Fund will seek excess return above the Benchmark through the active management of a short duration portfolio of highly liquid, high quality bonds.

The Fund will be an actively managed fund that seeks to achieve its investment objective by investing, under normal market conditions,[14] in exchange-traded commodity futures contracts, centrally cleared and non-centrally cleared swaps,[15] exchange-traded options on futures contracts, and exchange-traded commodity-linked instruments[16] (collectively, "Commodities") through a wholly-owned subsidiary controlled by the Fund and organized under the laws of the Cayman Islands ("Subsidiary"), thereby obtaining exposure to the commodities markets.

The Fund's Commodities investments, in part, will be comprised of exchange-traded futures contracts on commodities that comprise the Benchmark. Although the Fund, through the Subsidiary, will generally hold many of the futures contracts included in the Benchmark, the Fund and the Subsidiary will be actively managed and will not be obligated to invest in all of (or to limit investments solely to) such futures contracts. In addition, with respect to investments in exchange-traded futures contracts, the Fund and the Subsidiary will not be obligated to invest in the same amount or proportion as the Benchmark, or be obligated to track the performance of the Benchmark. In addition to exchange-traded futures contracts, the Fund's Commodities investments will also be comprised of the following: centrally cleared and non-centrally cleared swaps on commodities; exchange-traded options on futures contracts that provide exposure to the investment returns of the commodities markets; and exchange-traded commodity-linked instruments, without investing directly in physical commodities.

The Fund will invest in Commodities through investments in the Subsidiary and will not invest directly in physical commodities. The Fund's investment in the Subsidiary may not exceed 25% of the Fund's total assets. In addition to Commodities, the Fund's assets will be invested in: (1) short-term, investment grade fixed income securities, including only the following instruments: U.S. government and agency securities,[17] corporate debt obligations,[18] and repurchase agreements;[19] (2) money market instruments;[20] (3) investment

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[9] The Exchange represents that the Trust is registered under the Investment Company Act of 1940 ("1940 Act"). *See* Registration Statement on Form N–1A for the Trust, dated November 10, 2015 (File Nos. 333–201473 and 811–22926) ("Registration Statement"). The Exchange further states that the Trust has obtained certain exemptive relief under the 1940 Act.

[10] *See* BATS Rule 14.11(i)(7). The Exchange further represents that, in the event that (a) the Adviser or a Sub-Adviser becomes, or becomes newly affiliated with, a broker-dealer or registers as a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of, or changes to, the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding such portfolio.

[11] The Commission notes that additional information regarding the Fund, the Trust, the Subsidiary (as defined herein), and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value ("NAV"), distributions, and taxes, among other things, can be found in the Notice and the Registration Statement, as applicable. *See* Notice and Registration Statement, *supra* notes 3 and 9, respectively.

[12] The Benchmark is developed, maintained, and sponsored by S&P Dow Jones Indices LLC ("S&P Indices").

[13] According to the Exchange, the Benchmark currently contains 24 commodity futures on physical commodities across five sectors: energy, agriculture; livestock; industrial metals; and precious metals. *See* Notice, *supra* note 3 (providing additional information regarding the Benchmark and its components, including a table describing each of the commodities underlying the futures contracts included in the Benchmark as of October 31, 2015, and each instrument's trading hours, exchange, and ticker symbol).

[14] The term "under normal market conditions" includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets, futures markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance.

[15] Investments in non-centrally cleared swaps (through the Subsidiary) will not represent more than 20% of the Fund's net assets. When investing in non-centrally cleared swaps, the Subsidiary will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser and/or a Sub-Adviser will evaluate the creditworthiness of counterparties on an ongoing basis. In addition to information provided by credit agencies, the Adviser's and/or a Sub-Adviser's analysis will evaluate each approved counterparty using various methods of analysis and may consider such factors as the counterparty's liquidity, its reputation, the Adviser's and/or a Sub-Adviser's past experience with the counterparty, its known disciplinary history and its share of market participation.

[16] Exchange-traded commodity-linked instruments include only the following: (1) Funds that provide exposure to commodities as would be listed under Exchange Rules 14.11(b), (c), and (i); and (2) pooled investment vehicles that invest primarily in commodities and commodity-linked instruments as would be listed under Exchange Rules 14.11(d) and 14.11(e)(2), (4), (6), (7), (8), (9), and (10).

[17] Such securities are securities that are issued or guaranteed by the U.S. Treasury, by various agencies of the U.S. government, or by various instrumentalities, which have been established or sponsored by the U.S. government. U.S. Treasury obligations are backed by the "full faith and credit" of the U.S. government. Securities issued or guaranteed by federal agencies and U.S. government-sponsored instrumentalities may or may not be backed by the full faith and credit of the U.S. government.

[18] At least 75% of corporate debt obligations will have a minimum principal amount outstanding of $100 million or more.

[19] The Fund intends to enter into repurchase agreements only with financial institutions and dealers believed by the Adviser and/or a Sub-Adviser to present minimal credit risks in accordance with criteria approved by the Trust's Board of Trustees ("Board"). The Adviser and/or a Sub-Adviser will review and monitor the creditworthiness of such institutions. The Adviser and/or a Sub-Adviser will monitor the value of the collateral at the time the transaction is entered into and at all times during the term of the repurchase agreement.

[20] For the Fund's purposes, money market instruments will include only the following instruments: short-term, high-quality securities issued or guaranteed by non-U.S. governments, agencies and instrumentalities; non-convertible corporate debt securities with remaining maturities of not more than 397 days that satisfy ratings

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companies (other than those that are commodity-linked instruments),[21] including both exchange traded and non-exchange-traded investment companies, that provide exposure to commodities, equity securities, and fixed income securities to the extent permitted under the 1940 Act and any applicable exemptive relief; [22] (4) certain bank instruments; [23] and (5) cash and other cash equivalents (collectively, "Other Investments"). The Fund will use the Other Investments as investments, to provide liquidity, and to collateralize the Subsidiary's commodity exposure on a day-to-day basis.

The Fund's investment in the Subsidiary will be designed to help the Fund achieve exposure to commodity returns in a manner consistent with the federal tax requirements applicable to the Fund and other regulated investment companies. The Fund intends to qualify for, and to elect to be treated as, a separate regulated investment company under Subchapter M of the Internal Revenue Code.

B. Exchange's Description of the Subsidiary's Investments

The Subsidiary will generally seek to make investments in Commodities, and its portfolio will be managed by the Adviser or a Sub-Adviser.[24] The Adviser or a Sub-Adviser will use its discretion to determine the percentage of the Fund's assets allocated to the Commodities held by the Subsidiary that will be invested in exchange-traded commodity futures contracts, centrally cleared and non-centrally cleared swaps, exchange-traded options on futures contracts, and exchange-traded commodity-linked instruments. In this regard, under normal market conditions, the Subsidiary is expected, as a general matter, to invest in futures contracts in proportional weights and allocations that are similar to the Benchmark, as well as in the other Commodities. Additionally, the Subsidiary, like the Fund, may invest in Other Investments (*e.g.,* as investments, to serve as margin or collateral, or to otherwise support the Subsidiary's positions in Commodities).

The Fund's investment in the Subsidiary is intended to provide the Fund with exposure to commodity markets within the limits of current federal income tax laws applicable to investment companies such as the Fund, which limit the ability of investment companies to invest directly in the derivative instruments. The Subsidiary will have the same investment objective as the Fund, but unlike the Fund, it may invest without limitation in Commodities. The Subsidiary's investments will provide the Fund with exposure to domestic and international markets.

C. Exchange's Description of Commodities Regulation

The Commodity Futures Trading Commission ("CFTC") has adopted substantial amendments to CFTC Rule 4.5 relating to the permissible exemptions and conditions for reliance on exemptions from registration as a commodity pool operator. As a result of the instruments that will be indirectly held by the Fund, the Adviser will register as a commodity pool operator and will also become a member of the National Futures Association ("NFA"). Any Sub-Adviser will register as a commodity pool operator or commodity trading adviser, as required by CFTC regulations. The Fund and the Subsidiary will be subject to regulation by the CFTC and NFA and additional disclosure, reporting, and recordkeeping rules imposed upon commodity pools.

D. Exchange's Description of the Fund's Investment Restrictions

While the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2X and −3X) of the Benchmark. In addition, the Fund may not invest more than 25% of the value of its total assets in securities of issuers in any one industry or group of industries. This restriction will not apply to obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities, or securities of other investment companies.

The Subsidiary's shares will be offered only to the Fund, and the Fund will not sell shares of the Subsidiary to other investors. The Fund and the Subsidiary will not invest in any non-U.S. equity securities (other than shares of the Subsidiary). The Fund will not purchase securities of open-end or closed-end investment companies, except in compliance with the 1940 Act or any applicable exemptive relief. In addition, the Exchange represents that, with respect to the futures contracts and exchange-traded options on futures contracts in which the Subsidiary invests, not more than 10% of the weight (to be calculated as the value of the contract divided by the total absolute notional value of the Subsidiary's futures and options contracts) of the futures and options contracts held by the Subsidiary, in the aggregate, shall consist of instruments whose principal trading market is a market from which the Exchange may not obtain information regarding trading in the futures contracts and exchange-traded options on futures contracts by virtue of: (a) Its membership in the Intermarket Surveillance Group ("ISG"); or (b) a comprehensive surveillance sharing agreement.

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities deemed illiquid by the Adviser.[25] The

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requirements under Rule 2a-7 under the 1940 Act; money market mutual funds; and deposits and other obligations of U.S. and non-U.S. banks and financial institutions. In addition, the Fund may invest in commercial paper (short-term unsecured promissory notes), but only if the commercial paper has received the highest rating from at least one nationally recognized statistical rating organization or, if unrated, has been judged by the Adviser and/or a Sub-Adviser to be of comparable quality.

[21] According to the Exchange, the Fund may invest in the securities of certain other investment companies in excess of the limits imposed under the 1940 Act pursuant to an exemptive order obtained by the Trust and the Adviser from the Commission. The exchange-traded investment companies in which the Fund may invest include Index Fund Shares (as described in Rule 14.11(c)), Portfolio Depository Receipts (as described in Rule 14.11(b)), and Managed Fund Shares (as described in Rule 14.11(i)). The non-exchange-traded investment companies in which the Fund may invest include all non-exchange-traded investment companies that are not money market mutual funds, as described above. While the Fund and the Subsidiary may invest in inverse commodity-linked instruments and securities of investment companies, the Fund and the Subsidiary will not invest in leveraged or inverse leveraged (*e.g.,* 2X or -3X) commodity-linked instruments or securities of investment companies.

[22] The exchange-traded investment companies and commodity-linked instruments in which the Fund invests will be listed and traded in the U.S. on registered exchanges.

[23] The term "certain bank instruments" includes only the following instruments: certificates of deposit issued against funds deposited in a bank or savings and loan association; bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; and bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest.

[24] The Exchange states that the Subsidiary will not be registered under the 1940 Act and will not be directly subject to its investor protections, except as noted in the Registration Statement. However, the Subsidiary will be wholly-owned and controlled by the Fund. Therefore, the Fund's ownership and control of the Subsidiary will prevent the Subsidiary from taking action contrary to the interests of the Fund or its shareholders. The Board will have oversight responsibility for the investment activities of the Fund, including its expected investment in the Subsidiary, and the Fund's role as the sole shareholder of the Subsidiary. The Subsidiary will also enter into separate contracts for the provision of custody, transfer agency, and accounting agent services with the same or with affiliates of the same service providers that provide those services to the Fund.

[25] In reaching liquidity decisions, the Adviser may consider the following factors: The frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and

Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets, as determined in accordance with Commission staff guidance.

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act [26] and the rules and regulations thereunder applicable to a national securities exchange.[27] In particular, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[28] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act,[29] which sets forth the finding of Congress that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities. Quotation and last-sale information for the Shares will be available on the facilities of the Consolidated Tape Association ("CTA"). An estimated value, defined in BATS Rule 14.11(i)(3)(C) as the Intraday Indicative Value ("IIV"), that reflects an estimated intraday value of the Fund's portfolio (including the Subsidiary's portfolio), will be disseminated. The IIV will be based upon the current value for the components of the Disclosed Portfolio (as defined below) and will be updated and widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Exchange's Regular Trading Hours.[30] On each business day, before commencement of trading in Shares during Regular Trading Hours,[31] the Fund will disclose on its Web site the identities and quantities of the portfolio of securities, Commodities, and other assets ("Disclosed Portfolio" as defined in Rule 14.11(i)(3)(B)) held by the Fund and the Subsidiary that will form the basis for the Fund's calculation of NAV at the end of the business day.[32] The NAV of the Fund's Shares generally will be calculated once daily Monday through Friday as of the close of regular trading on the New York Stock Exchange, generally 4:00 p.m. Eastern Time.[33] Additionally, information regarding market price and volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will also be published daily in the financial section of newspapers. Intra-day executable price quotations on the securities and other assets held by the Fund and the Subsidiary will be available from major broker-dealer firms or on the exchange on which they are traded, as applicable. Intra-day price information on the securities and other assets held by the Fund and the Subsidiary will also be available through subscription services,

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the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace trades (*e.g.,* the time needed to dispose of the security, the method of soliciting offers, and the mechanics of transfer).

[26] 15 U.S.C. 78f.

[27] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 15 U.S.C. 78f(b)(5).

[29] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[30] According to the Exchange, several major market data vendors display and/or make widely available Intraday Indicative Values published via the CTA or other data feeds.

[31] Regular Trading Hours are 9:30 a.m. to 4:00 p.m. Eastern Time.

[32] According to the Exchange, the Fund's disclosure of derivative positions in the Disclosed Portfolio will include information that market participants can use to value these positions intraday. On a daily basis, the Disclosed Portfolio displayed on the Fund's Web site will include the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap), the identity of the security, commodity, or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value, or number of shares, contracts, or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site and information will be publicly available at no charge.

[33] In determining the value of the assets held by the Fund and the Subsidiary, the Fund's and the Subsidiary's investments will be generally valued using market valuations. A market valuation generally means a valuation (i) obtained from an exchange, a pricing service, or a major market maker (or dealer), (ii) based on a price quotation or other equivalent indication of value supplied by an exchange, a pricing service, or a major market maker (or dealer), or (iii) based on amortized cost. The Fund and the Subsidiary may use various pricing services or discontinue the use of any pricing service. A price obtained from a pricing service based on such pricing service's valuation matrix may be considered a market valuation. If available, debt securities and money market instruments with maturities of more than 60 days will typically be priced based on valuations provided by independent, third party pricing agents. Such values will generally reflect the last reported sales price if the security is actively traded. The third party pricing agents may also value debt securities at an evaluated bid price by employing methodologies that utilize actual market transactions, broker supplied valuations, or other methodologies designed to identify the market value for such securities. Debt obligations with remaining maturities of 60 days or less may be valued on the basis of amortized cost, which approximates market value. If such prices are not available, the security will be valued based on values supplied by independent brokers or by fair value pricing, as described below. Futures contracts will be valued at the settlement price established each day by the board or exchange on which they are traded. Exchange-traded options will be valued at the closing price in the market where such contracts are principally traded. Swaps will be valued based on valuations provided by independent, third-party pricing agents. Securities of non-exchange-traded investment companies will be valued at NAV. Equity securities listed on a securities exchange (including exchange-traded commodity linked instruments and exchange-traded investment companies), market or automated quotation system for which quotations are readily available (except for securities traded on The NASDAQ Stock Market LLC ("NASDAQ") and the London Stock Exchange Alternative Investment Market ("LSE AIM")) will be valued at the last reported sale price on the primary exchange or market on which they are traded on the valuation date (or at approximately 4:00 p.m. Eastern Time if a security's primary exchange is normally open at that time). For a security that trades on multiple exchanges, the primary exchange will generally be considered to be the exchange on which the security generally has the highest volume of trading activity. If it is not possible to determine the last reported sale price on the relevant exchange or market on the valuation date, the value of the security will be taken to be the most recent mean between the bid and asked prices on such exchange or market on the valuation date. Absent both bid and asked prices on such exchange, the bid price may be used. For securities traded on NASDAQ or LSE AIM, the official closing price will be used. If such prices are not available, the security will be valued based on values supplied by independent brokers or by fair value pricing, as described below. The prices for foreign instruments will be reported in local currency and converted to U.S. dollars using currency exchange rates. Exchange rates will be provided daily by recognized independent pricing agents. In the event that current market valuations are not readily available or such valuations do not reflect current market values, the affected investments will be valued using fair value pricing pursuant to the pricing policy and procedures approved by the Board in accordance with the 1940 Act. Fair value pricing may require subjective determinations about the value of an asset and may result in prices that differ from the value that would be realized if the asset was sold.

such as Bloomberg and Thomson Reuters, which can be accessed by authorized participants and other investors.[34] Daily trading volume information for the Fund will also be available in the financial section of newspapers, through subscription services such as Bloomberg, Thomson Reuters, and International Data Corporation, which can be accessed by authorized participants and other investors, as well as through other electronic services, including major public Web sites. The Fund's Web site will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Information relating to the Benchmark, including its constituents, weightings, and changes to its constituents, will be available on the Web site of S&P Indices.

The Commission further believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily, and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[35] Trading in the Shares also will be subject to BATS Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted.[36] The Exchange may halt trading in the Shares if trading is not occurring in the securities, Commodities, or other assets constituting the Disclosed Portfolio of the Fund and the Subsidiary, or if other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[37] Further, the Commission notes that the Reporting Authority that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.[38] The Exchange states that it prohibits the distribution of material, non-public information by its employees. The Exchange also represents that the Adviser is affiliated with a broker-dealer, and the Adviser has implemented a fire wall with respect to that broker-dealer affiliate regarding access to information concerning the composition of, or changes to, the Fund's portfolio.[39] Moreover, the Exchange represents that it may obtain information regarding trading in the Shares and the underlying shares in exchange-traded investment companies, commodity-linked instruments, futures, and options on futures via ISG, from other exchanges who are members or affiliates of ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

The Exchange further represents that the Shares are deemed to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. In support of this proposal, the Exchange has made representations, including:

(1) The Shares will be subject to BATS Rule 14.11(i), which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares.

(4) The Exchange will communicate as needed regarding trading in the Shares and in the exchange-traded Commodities and exchange-traded investment companies not included within the definition of Commodities (together, "Exchange Traded Instruments") held by the Fund and the Subsidiary with other markets and other entities that are members of ISG and may obtain trading information regarding trading in the Shares and in the Exchange Traded Instruments held by the Fund and the Subsidiary from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and in the Exchange Traded Instruments held by the Fund and the Subsidiary from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. The Exchange also will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

(5) With respect to the futures contracts and exchange-traded options on futures contracts in which the Subsidiary invests, not more than 10% of the weight (to be calculated as the value of the contract divided by the total absolute notional value of the Subsidiary's futures and options contracts) of the futures and options contracts held by the Subsidiary, in the aggregate, shall consist of instruments whose principal trading market is a market from which the Exchange may not obtain information regarding trading in the futures contracts and exchange-

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[34] More specifically, the Exchange represents that pricing information for exchange-traded commodity futures contracts, exchange-traded options on futures contracts, exchange-traded commodity-linked instruments, exchange-traded investment companies other than exchange-traded commodity-linked instruments will be available on the exchanges on which they are traded and through subscription services. Pricing information for securities of non-exchange-traded investment companies will be available through the applicable fund's Web site or major market data vendors. Pricing information for swaps, fixed income securities, and money market instruments will be available through subscription services, broker-dealer firms, and/or pricing services. Additionally, the Trade Reporting and Compliance Engine ("TRACE") of the Financial Industry Regulatory Authority ("FINRA") will be a source of price information for certain fixed income securities held by the Fund.

[35] *See* BATS Rule 14.11(i)(4)(A)(ii).

[36] *See* BATS Rule 14.11(i)(4)(B)(iv).

[37] *See* BATS Rule 14.11(i)(4)(B)(iii) (providing additional considerations for the suspension of trading in or removal from listing of Managed Fund Shares on the Exchange). With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. The Exchange will halt trading in the Shares under the conditions specified in BATS Rule 11.18. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable.

[38] *See* BATS Rule 14.11(i)(4)(B)(ii)(B).

[39] *See supra* note 10 and accompanying text. An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 ("Advisers Act"). As a result, the Adviser and any Sub-Adviser and their related personnel are subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

traded options on futures contracts by virtue of: (a) Its membership in ISG; or (b) a comprehensive surveillance sharing agreement.

(6) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular ("Circular") of the special characteristics and risks associated with trading the Shares. Specifically, the Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) BATS Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (c) how information regarding the IIV and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Opening[40] and After Hours Trading Sessions[41] when an updated IIV will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(7) For initial and continued listing, the Fund and the Subsidiary must be in compliance with Rule 10A–3 under the Act.[42]

(8) The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including securities deemed illiquid by the Adviser under the 1940 Act.

(9) The Fund will invest in Commodities through investments in the Subsidiary and will not invest directly in physical commodities. The Fund's investment in the Subsidiary may not exceed 25% of the Fund's total assets. The Fund and the Subsidiary will not invest in any non-U.S. equity securities (other than shares of the Subsidiary).

(10) Investments in non-centrally cleared swaps (through the Subsidiary) will not represent more than 20% of the Fund's net assets.

(11) At least 75% of corporate debt obligations will have a minimum principal amount outstanding of $100 million or more. In addition, the exchange-traded investment companies and commodity-linked instruments in which the Fund invests will be listed and traded in the U.S. on registered exchanges.

(12) While the Fund will be permitted to borrow as permitted under the 1940 Act, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*i.e.,* 2X and −3X) of the Benchmark.

(13) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

The Exchange represents that all statements and representations made in the filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. This approval order is based on all of the Exchange's representations and description of the Fund, including those set forth above and in the Notice. The Commission notes that the Fund and the Shares must comply with the requirements of BATS Rule 14.11(i), including those set forth in this proposed rule change, to be listed and traded on the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto, is consistent with Section 6(b)(5) of the Act[43] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[44] that the proposed rule change (SR–BATS–2015–105), as modified by Amendment Nos. 1, 2, and 3 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Robert W. Errett,

Deputy Secretary.

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[40] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[41] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[42] *See* 17 CFR 240.10A–3.

[43] 15 U.S.C. 78f(b)(5).

[44] 15 U.S.C. 78s(b)(2).

[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77488; File No. SR–ISEGemini–2016–03]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Filing of Proposed Rule Change Related to Market Wide Risk Protection

March 31, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on March 17, 2016, the ISE Gemini, LLC (the "Exchange" or "ISE Gemini") filed with the Securities and Exchange Commission ("Commission") the proposed rule change, as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to introduce new activity based order protections as described in more detail below. The text of the proposed rule change is available on the Exchange's Web site (*http://www.ise.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to introduce new risk protections for orders designed to aid members in their risk management by supplementing current price reasonability checks with activity based order protections.[3] In particular, the Exchange proposes to introduce two activity based risk protections that will be mandatory for all members: (1) The "Order Entry Rate Protection," which protects members against *entering* orders at a rate that exceeds predefined thresholds,[4] and (2) the "Order Execution Rate Protection," which protects members against *executing* orders at a rate that exceeds their predefined risk settings. Both of these risk protections are detailed in Proposed Rule 714(d), "Market Wide Risk Protection."[5] The Exchange will announce the implementation date of the Market Wide Risk Protection in a circular to be distributed to members prior to implementation.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Pursuant to the proposed Market Wide Risk Protection rule, the Exchange's trading system (the "System") will maintain one or more counting programs on behalf of each member that will count the number of orders entered, and the number of contracts traded on ISE Gemini or, if chosen by the member,[6] across both ISE Gemini and ISE Gemini's affiliate, the International Securities Exchange, LLC ("ISE"), which shares a trading system with ISE Gemini. Members can use multiple counting programs to separate risk protections for different groups established within the member.[7] The counting programs will maintain separate counts, over rolling time periods specified by the member for each count, of: (1) The total number of orders entered; and (2) the total number of contracts traded.[8] Contracts executed on the agency and contra-side of a two-sided crossing order will be counted separately for the Order Execution Rate Protection.

Members will have discretion to establish the applicable time period for each of the counts maintained under the Market Wide Risk Protection, provided that the selected period must be within minimum and maximum parameters established by the Exchange and announced via circular.[9] While the Market Wide Risk Protection is mandatory for all members, the Exchange is not proposing to establish minimum or maximum values for the order entry and execution parameters described in (1) and (2) above. The Exchange believes that this approach will give members the flexibility needed to appropriately tailor the Market Wide Risk Protection to their respective risk management needs. In this regard, the Exchange notes that each member is in the best position to determine risk settings appropriate for their firm based on the member's trading activity and business needs. In the interest of maintaining a fair and orderly market, however, the Exchange will establish default values for the applicable time period and order entry and execution parameters in a circular to be distributed to members. Default values established by the Exchange will apply only to members that do not submit their own parameters for the Market Wide Risk Protection.

The System will trigger the Market Wide Risk Protection when the counting program has determined that the member has either (1) entered during the specified time period a number of orders exceeding its designated allowable order rate, or (2) executed during the specified time period a number of contracts exceeding its designated allowable contract execution rate. In particular, after a member enters an order, or a member's order is executed, the System will look back over the specified time period to determine whether the member has exceeded the threshold that it has set for the total number of orders entered or the total number of contracts traded, as applicable. If the member's threshold has been exceeded, the Market Wide Risk Protection will be triggered and the System will automatically reject all subsequent incoming orders entered by the member on ISE Gemini or, if applicable, across both ISE Gemini and ISE.[10] In addition, if the member has opted in to this functionality, the System will automatically cancel all of the member's existing orders. The Market Wide Risk Protection will remain engaged until the member manually (*e.g.*, via email) notifies the Exchange to enable the acceptance of new orders; however, the System will still allow members to interact with existing orders entered before the protection was triggered, including sending cancel order messages and receiving trade executions for those orders.

The Exchange believes that the proposed Market Wide Risk Protection will assist members in better managing their risk when trading on ISE Gemini. In particular, the proposed rule change provides functionality that allows members to set risk management thresholds for the number of orders entered or contracts executed on the Exchange during a specified period. This is similar to how other options exchanges have implemented activity-based risk management protections,[11] and the Exchange believes this functionality will likewise be beneficial for ISE Gemini members.

The examples below illustrate how the Market Wide Risk Protection would work both for order entry and order execution protections:

Example 1, Order Entry Rate Protection:

Broker Dealer 1 ("BD1") designates an allowable order rate of 499 orders/1 second.

@0 milliseconds, BD1 enters 200 orders. (Order total: 200 orders)
@450 milliseconds, BD1 enters 250 orders. (Order total: 450 orders)
@950 milliseconds, BD1 enters 50 orders. (Order total: 500 orders)

Market Wide Risk Protection is triggered on ISE Gemini, and, if applicable, ISE[12] due to exceeding 499 orders in 1 second. All subsequent orders are rejected, and if BD1 has opted in to this functionality, all existing orders are cancelled. BD1 must contact Market Operations to resume trading.

Example 2, Order Execution Rate Protection:

BD1 designates an allowable execution rate of 15,000 contracts/2 seconds.

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[3] The Exchange provides members with limit order price protections designed to prevent erroneous executions by rejecting orders priced too far through the market. *See* Rule 714(b)(2).

[4] The Exchange will determine when to initiate the Order Entry Rate Protection pre-open to allow members time to load their orders without inadvertently triggering the protection. The precise time will be established by the Exchange and communicated to members via circular prior to implementation.

[5] The term "Market Wide Risk Protection" includes both the "Order Entry Rate Protection" and the "Order Execution Rate Protection."

[6] Members will have the option to set different risk parameters for their trading activity on each exchange, or set risk parameters that apply to their trading across both ISE Gemini and ISE, if desired.

[7] The Exchange will explain how members can go about setting up risk protections for different groups (*e.g.*, business units) in a circular issued to members.

[8] The member's allowable order rate for the Order Entry Rate Protection is comprised of the parameter defined in (1), while the allowable contract execution rate for the Order Execution Rate Protection is comprised of the parameter defined in (2).

[9] The Exchange anticipates that the minimum and maximum values for the applicable time period will be initially set at one second and a full trading day, respectively.

[10] Members that set different risk parameters for ISE Gemini and ISE will only have their orders rejected on the exchange whose threshold was exceeded.

[11] *See* Securities Exchange Act Release Nos. 74118 (January 22, 2015), 80 FR 4605 (January 28, 2015) (Notice); 74496 (March 13, 2015), 80 FR 14421 (March 19, 2015) (Approval) (SR–MIAX–2015–03).

[12] Members that share risk settings across both ISE Gemini and ISE will have the Market Wide Risk Protection triggered on both markets.

@0 milliseconds, BD1 receives executions for 5,000 contracts. (Execution total: 5,000 contracts)
@600 milliseconds, BD1 receives executions for 10,000 contracts. (Execution total: 15,000 contracts)
@1550 milliseconds, BD1 receives executions for 2,000 contracts. (Execution total: 17,000 contracts)

Market Wide Risk Protection is triggered on ISE Gemini, and, if applicable, ISE [13] due to exceeding 15,000 contracts in 2 seconds. All subsequent orders are rejected, and if BD1 has opted in to this functionality, all existing orders are cancelled. BD1 must contact Market Operations to resume trading.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[14] Specifically, the proposed rule change is consistent with Section 6(b)(5) of the Act,[15] because it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would assist with the maintenance of a fair and orderly market by establishing new activity based risk protections for orders. The Exchange currently offers a risk protection mechanism for market maker quotes that removes the member's quotes if a specified number of curtailment events occur during a set time period ("Market Wide Speed Bump").[16] The Exchange believes that this Market Wide Speed Bump functionality has been successful in reducing market maker risk and now proposes to adopt risk protections for orders that would allow other members to properly manage their exposure to excessive risk. In particular, the proposed rule change would implement two new risk protections based on the rate of order entry and order execution, respectively. The Exchange believes that both of these new protections, which together encompass the proposed Market Wide Risk Protection, would enable members to better manage their risk when trading options on the Exchange by limiting the member's risk exposure when systems or other issues result in orders being entered or executed at a rate that exceeds predefined thresholds. In today's market the Exchange believes that robust risk management is becoming increasingly more important for all members. The proposed rule change would provide an additional layer of risk protection for market participants that trade on the Exchange.

The proposed Market Wide Risk Protection is similar to risk management functionality provided by other options exchanges, including, for example, the MIAX Options Exchange ("MIAX"), which recently received Commission approval for its "Risk Protection Monitor" for orders.[17] In particular, the Market Wide Risk Protection is designed to reduce risk associated with system errors or market events that may cause members to send a large number of orders, or receive multiple, automatic executions, before they can adjust their exposure in the market. Without adequate risk management tools, such as those proposed in this filing, members could reduce the amount of order flow and liquidity that they provide. Such actions may undermine the quality of the markets available to customers and other market participants. Accordingly, the proposed rule change is designed to encourage members to submit additional order flow and liquidity to the Exchange, thereby removing impediments to and perfect [sic] the mechanisms of a free and open market and a national market system and, in general, protecting investors and the public interest. In addition, providing members with more tools for managing risk will facilitate transactions in securities because, as noted above, the members will have more confidence that protections are in place that reduce the risks from potential system errors and market events. As a result, the new functionality has the potential to promote just and equitable principles of trade.

The Exchange also believes that it is consistent with the protection of investors and the public interest to offer the Market Wide Risk Protection to members across both ISE Gemini and ISE as this will permit members to more effectively manage their risk simultaneously on both markets if desired. The Exchange already offers cross market risk protections for market makers [sic] quotes,[18] and is now proposing to similarly offer a cross market risk protection for orders in order to reduce the risk that members face when entering orders on multiple exchanges. The Exchange notes that issues that would trigger the Market Wide Risk Protection are not normally confined to a member's activity on a single exchange. Accordingly, the Exchange believes that offering the Market Wide Risk Protection on a cross-market basis would help members to more effectively manage their risk when trading on multiple markets, and reduce disruptive trading events to the benefit of all members and investors.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange does not believe that the proposed rule change would impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed Market Wide Risk Protection is similar to risk protections already available on other options exchanges,[20] and is designed to be a competitive offering that would mitigate the risk associated with trading on the Exchange. Market makers already benefit from Market Wide Speed Bump functionality available for quotes. The proposed change would extend new risk protections to orders so that additional market participants can benefit from risk mitigating functionality. Like the Exchange's Market Wide Speed Bump, the proposed rule change would also be offered cross-market to members that want to be protected from inadvertent exposure to excessive risk when trading on both ISE Gemini and ISE. Permitting this functionality to be cross-market will not have any impact on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In addition, the proposed functionality would be mandatory for all members, and would be made available on an equal and non-discriminatory basis. As such, the Exchange does not believe that the proposed rule change would impose any unnecessary burden on competition.

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[13] Members that share risk settings across both ISE Gemini and ISE will have the Market Wide Risk Protection triggered on both markets.

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *See* Rule 804(g)(2).

[17] *See* supra note 9 [sic].

[18] *See* Securities Exchange Act Release Nos. 71758 (March 20, 2014), 79 FR 16846 (March 26, 2014) ("Notice"); 73148 (September 19, 2014), 79 FR 57626 (September 25, 2014) (Approval) (SR–ISE Gemini–2014–09).

[19] 15 U.S.C. 78f(b)(8).

[20] *See* supra notes 10 [sic] and 15 [sic].

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the publication date of this notice or within such longer period (1) as the Commission may designate up to 45 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (2) as to which the self-regulatory organization consents, the Commission will:

(a) by order approve or disapprove such proposed rule change; or

(b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ISEGemini–2016–03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISEGemini–2016–03. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISEGemini–2016–03 and should be submitted on or before April 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07833 Filed 4–5–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77484; File No. SR–NYSEARCA–2016–52]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Adopting Requirements for the Collection and Transmission of Data Pursuant to Appendices B and C of the Regulation NMS Plan To Implement a Tick Size Pilot Program

March 31, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 29, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt requirements for the collection and transmission of data pursuant to Appendices B and C of the Regulation NMS Plan to Implement a Tick Size Pilot Program ("Plan"). The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE Group, Inc., on behalf of the Exchange, New York Stock Exchange LLC, NYSE MKT LLC, the Bats BZX Exchange, Inc. f/k/a BATS Exchange, Inc. ("BZX"), BATS BYX Exchange, Inc. f/k/a BATS Y-Exchange, Inc. ("BYX"), Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., Chicago Stock Exchange, Inc., Financial Industry Regulatory Authority, Inc. ("FINRA"), NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, and the Nasdaq Stock Market LLC (collectively "Participants"), filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder,[5] the Plan to Implement a Tick Size Pilot Program ("Pilot").[6] The Participants filed the Plan to comply with an order issued by the Commission on June 24,

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[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78k–1.

[5] 17 CFR 242.608.

[6] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

2014.[7] The Plan[8] was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[9]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stocks of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its members, as applicable, with the provisions of the Plan. As is described more fully below, the proposed rules would require ETP Holders[10] to comply with the applicable data collection requirements of the Plan.[11]

The Pilot will include stocks of companies with $3 billion or less in market capitalization, an average daily trading volume of one million shares or less, and a volume weighted average price of at least $2.00 for every trading day. The Pilot will consist of a control group of approximately 1400 Pilot Securities and three test groups with 400 Pilot Securities in each (selected by a stratified random sampling process).[12] During the pilot, Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group ("Test Group One") will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[13] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[14] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[15] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[16] will apply to the Trade-at requirement.

In approving the Plan, the Commission noted that the Trading Center data reporting requirements would facilitate an analysis of the effects of the Pilot on liquidity (*e.g.*, transaction costs by order size), execution quality (*e.g.*, speed of order executions), market maker activity, competition between trading venues (*e.g.*, routing frequency of market orders), transparency (*e.g.*, choice between displayed and hidden orders), and market dynamics (*e.g.*, rates and speed of order cancellations).[17] The Commission noted that Market Maker profitability data would assist the Commission in evaluating the effect, if any, of a widened tick increment on market marker profits and any corresponding changes in the liquidity of small-capitalization securities.[18]

Compliance with the Data Collection Requirements of the Plan

The Plan contains requirements for collecting and transmitting data to the Commission and to the public.[19] Specifically, Appendix B.I of the Plan (Market Quality Statistics) requires Trading Centers[20] to submit variety of market quality statistics, including information about an order's original size, whether the order was displayable or not, the cumulative number of orders, the cumulative number of shares of orders, and the cumulative number of shares executed within specific time increments, *e.g.*, from 30 seconds to less than 60 seconds after the time of order receipt. This information shall be categorized by security, order type, original order size, hidden status, and coverage under Rule 605.[21] Appendix B.I of the Plan also contains additional requirements for market orders and marketable limit orders, including the share-weighted average effective spread for executions of orders; the cumulative number of shares of orders executed with price improvement; and, for shares executed with price improvement, the share-weighted average amount per share that prices were improved.

Appendix B.II of the Plan (Market and Marketable Limit Order Data) requires Trading Centers to submit information relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, the National Best Bid and National Best Offer ("NBBO") quoted price, the NBBO quoted depth, the average execution price-share-weighted average, and the average execution time-share-weighted average.

The Plan requires Appendix B.I and B.II data to be submitted by Participants that operate a Trading Center, and by members of the Participants that operate Trading Centers. The Plan provides that each Participant that is the Designated Examining Authority ("DEA") for a member of the Participant that operates a Trading Center shall collect such data in a pipe delimited format, beginning six months prior to the Pilot Period and ending six months after the end of the Pilot Period. The Plan also requires the Participant, operating as DEA, to transmit this information to the SEC within 30 calendar days following month end.

The Exchange is proposing new Rule 7.46(b) to set forth the requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan. Proposed Rule 7.46(b) is substantially similar to the proposed rule changes by BZX that were recently approved by the Commission to adopt BZX Rule 11.27(b) which also sets forth requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan.[22]

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[7] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[8] Unless otherwise specified, capitalized terms used in this rule filing are based on the defined terms of the Plan.

[9] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) ("Approval Order").

[10] The term ETP Holder is defined in NYSE Arca Equities Rule 1.1(n) to mean a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing that has been issued an ETP. An ETP Holder must be a registered broker or dealer pursuant to Section 15 of the Act. An ETP Holder shall agree to be bound by the Certificate of Incorporation, Bylaws and Rules of NYSE Arca Equities, and by all applicable rules and regulations of the Commission.

The term ETP is defined in NYSE Arca Equities Rule 1.1(m) to mean an equity trading permit issued by NYSE Arca Equities for effecting approved securities transactions on NYSE Arca Equities' trading facilities.

[11] The Exchange proposes to provide in the introduction paragraph to NYSE Arca Equities Rule 7.46 ("Rule 7.46") that the Rule shall be in effect during a pilot period to coincide with the pilot period for the Plan (including any extensions to the pilot period for the Plan).

[12] *See* Section V of the Plan for identification of Pilot Securities, including criteria for selection and grouping.

[13] *See* Section VI(B) of the Plan.

[14] *See* Section VI(C) of the Plan.

[15] *See* Section VI(D) of the Plan.

[16] 17 CFR 242.611.

[17] *See* Approval Order, 80 FR at 27543.

[18] *Id.*

[19] The Exchange is also required by the Plan to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with applicable quoting and trading requirements specified in the Plan. The Exchange plans to separately propose Rules 7.46(a) and 7.46(c)–(e) that would require compliance by its ETP Holders with the applicable quoting and trading requirements specified in the Plan and has reserved Rules 7.46(a) and 7.46(c)–(e) for this purpose. *See, e.g.*, Securities Exchange Act Release No. 76229 (October 22, 2015), 80 FR 66065 (October 28, 2015) (SR–NYSE–2015–46) ("Quoting & Trading Rules Proposal"), as amended by Partial Amendment No. 1 to the Quoting & Trading Rules Proposal.

[20] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[21] 17 CFR 242.605.

Proposed Rule 7.46(b)(1) requires that an ETP Holder that operates a Trading Center shall establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the data collection and transmission requirements of Items I and II to Appendix B of the Plan, and an ETP Holder that is a Market Maker shall establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the data collection and transmission requirements of Item IV of Appendix B of the Plan and Item I of Appendix C of the Plan.

Proposed Rule 7.46(b)(2) provides that the Exchange shall collect and transmit to the SEC the data described in Items I and II of Appendix B of the Plan relating to trading activity in Pre-Pilot Data Collection Securities[23] and Pilot Securities on a Trading Center operated by the Exchange. The Exchange shall transmit such data to the SEC in a pipe delimited format, on a disaggregated basis by Trading Center, within 30 calendar days following month end for: (i) Each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) each Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period. The Exchange also shall make such data publicly available on the Exchange Web site on a monthly basis at no charge and will not identify the ETP Holder that generated the data.

Appendix B.IV (Daily Market Maker Participation Statistics) requires a Participant to collect data related to Market Maker participation from each Market Maker[24] engaging in trading activity on a Trading Center operated by the Participant. The Exchange is therefore proposing Rule 7.46(b)(3) to gather data about a Market Maker's participation in Pilot Securities and Pre-Pilot Data Collection Securities. Proposed Rule 7.46(b)(3)(A) provides that an ETP Holder that is a Market Maker shall collect and transmit to their DEA data relating to Item IV of Appendix B of the Plan with respect to activity conducted on any Trading Center in Pilot Securities and Pre-Pilot Data Collection Securities in furtherance of its status as a registered Market Maker, including a Trading Center that executes trades otherwise than on a national securities exchange, for transactions that have settled or reached settlement date. The proposed rule requires Market Makers to transmit such data in a format required by their DEA, by 12:00 p.m. EST on T+4 for: (i) Transactions in each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) for transactions in each Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period.

The Exchange understands that some ETP Holders may utilize a DEA that is not a Participant to the Plan and that their DEA would not be subject to the Plan's data collection requirements. In such case, a DEA that is not a Participant of the Plan would not be required to collect the required data and may not establish procedures for which ETP Holders it acts a DEA for to report the data required under subparagraphs (b)(3)(A) of Rule 7.46 and in accordance with Item IV of Appendix B of the Plan. Therefore, the Exchange proposes to adopt subparagraph (b)(3)(B) to Rule 7.46 to require an ETP Holder that is a Market Maker whose DEA is not a Participant to the Plan to transmit the data collected pursuant to paragraph (3)(A) of Rule 7.46(b) to FINRA, which is a Participant to the Plan and is to collect data relating to Item IV of Appendix B of the Plan on behalf of the Participants. For Market Makers for which it is the DEA, FINRA issued a Market Maker Transaction Data Technical Specification to collect data on Pre-Pilot Data Collection Securities and Pilot Securities from Trading Centers to comply with the Plan's data collection requirements.[25]

Proposed Rule 7.46(b)(3)(C) provides that the Exchange shall transmit the data collected by the DEA or FINRA pursuant to Rule 7.46(b)(3)(A) and (B) above relating to Market Maker activity on a Trading Center operated by the Exchange to the SEC in a pipe delimited format within 30 calendar days following month end. The Exchange shall also make such data publicly available on the Exchange Web site on a monthly basis at no charge and shall not identify the Trading Center that generated the data.

Appendix C.I (Market Maker Profitability) requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Specifically, the Participant is required to collect the total number of shares of orders executed by the Market Maker; the raw Market Maker realized trading profits, and the raw Market Maker unrealized trading profits. Data shall be collected for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. This data shall be collected on a monthly basis, to be provided in a pipe delimited format to the Participant, as DEA, within 30 calendar days following month end. Appendix C.II (Aggregated Market Maker Profitability) requires the Participant, as DEA, to aggregate the Appendix C.I data, and to categorize this data by security as well as by the control group and each Test Group. That aggregated data shall contain information relating to total raw Market Maker realized trading profits, volume-weighted average of raw Market Maker realized trading profits, the total raw Market Maker unrealized trading profits, and the volume-weighted average of Market Maker unrealized trading profits.

The Exchange is therefore proposing Rule 7.46(b)(4) to set forth the requirements for the collection and transmission of data pursuant to Appendix C.I of the Plan. Proposed Rule 7.46(b)(4)(A) requires that an ETP Holder that is a Market Maker shall collect and transmit to their DEA the data described in Item I of Appendix C of the Plan with respect to executions in Pilot Securities that have settled or reached settlement date that were executed on any Trading Center. The proposed rule also requires ETP Holders to provide such data in a format required by their DEA by 12 p.m. EST on T+4 for executions during and outside of Regular Trading Hours in each: (i) Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period.

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[22] *See* Securities Exchange Act Release Nos. 77105 (February 10, 2016), 81 FR 8112 (February 17, 2016) (order approving SR–BATS–2015–102); and 77310 (March 7, 2016) (notice for comment and immediate effectiveness of SR–BATS–2016–27).

[23] The Exchange is proposing *Commentary* .90 to proposed Rule 7.46(b) to define "Pre-Pilot Data Collection Securities" as the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C of the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Participants shall compile the list of Pre-Pilot Data Collection Securities by selecting all NMS stocks with a market capitalization of $5 billion or less, a Consolidated Average Daily Volume (CADV) of 2 million shares or less and a closing price of $1 per share or more. The market capitalization and the closing price thresholds shall be applied to the last day of the pre-pilot measurement period, and the CADV threshold shall be applied to the duration of the pre-pilot measurement period. The pre-pilot measurement period shall be the three calendar months ending on the day when the Pre-Pilot Data Collection Securities are selected. The Pre-Pilot Data Collection Securities shall be selected thirty days prior to the commencement of the six-month pre-pilot period. On the trading day that is the first trading day of the Pilot Period through six months after the end of the Pilot Period, the data collection requirements will become applicable to the Pilot Securities only.

[24] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

[25] FINRA members for which FINRA is their DEA should refer to the Market Maker Transaction Data Technical Specification on the FINRA Web site at *http://www.finra.org/sites/default/files/market-maker-transaction-data-tech-specs.pdf.*

For the same reasons set forth above for subparagraph (b)(3)(B) to Rule 7.46, the Exchange proposes to adopt subparagraph (b)(4)(B) to Rule 7.46 to require an ETP Holder that is a Market Maker whose DEA is not a Participant to the Plan to transmit the data collected pursuant to paragraph (4)(A) of Rule 7.46(b) to FINRA. As stated above, FINRA is a Participant to the Plan and is to collect data relating to Item I of Appendix C of the Plan on behalf of the Participants. For Market Makers for which it is the DEA, FINRA issued a Market Maker Transaction Data Technical Specification to collect data on Pre-Pilot Data Collection Securities and Pilot Securities from Trading Centers to comply with the Plan's data collection requirements.[26]

The Exchange is also adopting a rule setting forth the manner in which Market Maker participation will be calculated. Item III of Appendix B of the Plan requires each Participant that is a national securities exchange to collect daily Market Maker registration statistics categorized by security, including the following information: (i) Ticker symbol; (ii) the Participant exchange; (iii) number of registered market makers; and (iv) the number of other registered liquidity providers. Therefore, the Exchange proposes to adopt Rule 7.46(b)(5) providing that the Exchange shall collect and transmit to the SEC the data described in Item III of Appendix B of the Plan relating to daily Market Maker registration statistics in a pipe delimited format within 30 calendar days following month end for: (i) Transactions in each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) transactions in each Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period.

The Exchange is also proposing, through *Commentary* to proposed Rule 7.46(b), to clarify other aspects of the data collection requirements. *Commentary* .10 to proposed Rule 7.46(b) relates to the use of the retail investor order flag for purposes of Appendix B.II(n) reporting. The Plan currently states that market and marketable limit orders shall include a "yes/no" field relating to the Retail Investor Order flag. The Exchange is proposing *Commentary* .10 to proposed Rule 7.46(b) to clarify that, for purposes of the reporting requirement in Appendix B.II(n), a Trading Center shall report "y" to their DEA where it is relying upon the Retail Investor Order exception to Test Groups Two and Three, and "n" for all other instances.[27] The Exchange believes that requiring the identification of a Retail Investor Orders only where the exception may apply (*i.e.*, Pilot Securities in Test Groups Two and Three) is consistent with Appendix B.II(n).

Commentary .20 to proposed Rule 7.46(b) requires that ETP Holders populate a field to identify to their DEA whether an order is affected by the bands in place pursuant to the National Market System Plan to Address Extraordinary Market Volatility.[28] Pursuant to the Limit-Up Limit-Down Plan, between 9:30 a.m. and 4:00 p.m., the Securities Information Processor ("SIP") calculates a lower price band and an upper price band for each NMS stock. These price bands represent a specified percentage above or below the stock's reference price, which generally is calculated based on reported transactions in that stock over the preceding five minutes. When one side of the market for an individual security is outside the applicable price band, the SIP identifies that quotation as non-executable. When the other side of the market reaches the applicable price band (*e.g.*, the offer reaches the lower price band), the security enters a Limit State. The stock would exit a Limit State if, within 15 seconds of entering the Limit State, all Limit State Quotations were executed or canceled in their entirety. If the security does not exit a Limit State within 15 seconds, then the primary listing exchange declares a five-minute trading pause, which would be applicable to all markets trading the security.

The Exchange and the other Participants have determined that it is appropriate to create a new flag for reporting orders that are affected by the Limit-Up Limit-Down bands. Accordingly, a Trading Center shall report a value of "Y" to their DEA when the ability of an order to execute has been affected by the Limit-Up Limit-Down bands in effect at the time of order receipt. A Trading Center shall report a value of "N" to their DEA when the ability of an order to execute has not been affected by the Limit-Up Limit-Down bands in effect at the time of order receipt.

Commentary .20 to proposed Rule 7.46(b) also requires, for securities that may trade in a foreign market, that the Participant indicate whether the order was handled domestically, or routed to a foreign venue. Accordingly, the Participant will indicate, for purposes of Appendix B.I, whether the order was: (1) Fully executed domestically, or (2) fully or partially executed on a foreign market. For purposes of Appendix B.II, the Participant will classify all orders in securities that may trade in a foreign market Pilot and Pre-Pilot Securities as: (1) Directed to a domestic venue for execution; (2) may only be directed to a foreign venue for execution; or (3) was fully or partially directed to a foreign venue at the discretion of the member. The Exchange believes that this proposed flag will better identify orders in securities that may trade in a foreign market, as such orders that were routed to foreign venues would not be subject to the Plan's quoting and trading requirements, and could otherwise compromise the integrity of the data.

Commentary .30 to proposed Rule 7.46(b) relates to the time ranges specified in Appendix B.I.a(14), B.I.a(15), B.I.a(21) and B.I.a(22).[29] The

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[26] *Id.*

[27] FINRA, on behalf of the Plan Participants submitted a letter to Commission requesting exemption from certain provisions of the Plan related to data collection. *See* letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA dated December 9, 2015 to Robert W. Errett, Deputy Secretary, Commission ("Exemption Request"). The Commission, pursuant to its authority under Rule 608(e) of Regulation NMS, granted BZX a limited exemption from the requirement to comply with certain provisions of the Plan as specified in the letter and noted herein. *See* letter from David Shillman, Associate Director, Division of Trading and Markets, Commission to Eric Swanson, General Counsel, BZX, dated February 10, 2016 ("Exemption Letter").

[28] *See* National Market System Plan to Address Extraordinary Market Volatility, Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) ("Limit-Up Limit-Down Plan").

[29] Specifically, Appendix B.I.a(14) requires reporting of the cumulative number of shares of orders executed from 0 to less than 100 microseconds after the time of order receipt; Appendix B.I.a(15) requires reporting of the cumulative number of shares of orders executed from 100 microseconds to less than 100 milliseconds after the time of order receipt; Appendix B.I.a(21) requires reporting of the cumulative number of shares of orders cancelled

Continued

Exchange and the other Participants have determined that it is appropriate to change the reporting times in these provisions to require more granular reporting for these categories. Accordingly, the Exchange proposes to add Appendix B.I.a(14A), which will require Trading Centers to report the cumulative number of shares of orders executed from 100 microseconds to less than 1 millisecond after the time of order receipt. Appendix B.I.a(15) will be changed to require the cumulative number of shares of orders executed from 1 millisecond to less than 100 milliseconds after the time of order receipt. The Exchange also proposes to add Appendix B.I.a(21A), which will require Trading Centers to report the cumulative number of shares of orders canceled from 100 microseconds to less than 1 millisecond after the time of order receipt. Appendix B.I.a(22) will be changed to require the cumulative number of shares of orders canceled from 1 millisecond to less than 100 milliseconds after the time of order receipt. The Exchange believes that these new reporting requirements will contribute to a meaningful analysis of the Pilot by producing more granular data on these points.[30]

Commentary .40 to proposed Rule 7.46(b) relates to the relevant measurement for purposes of Appendix B.I.a(31)–(33) reporting. Currently, the Plan states that this data shall be reported as of the time of order execution. The Exchange and the other Participants believe that this information should more properly be captured at the time of order receipt as evaluating share-weighted average prices at the time of order receipt is more consistent with the goal of observing the effect of the Pilot on the liquidity of Pilot Securities. The Exchange is therefore proposing to make this change through *Commentary* .40 to proposed Rule 7.46(b).[31] This change will make these provisions consistent with the remainder of the statistics in Appendix B.I.a, which are all based on order receipt.

Commentary .50 to proposed Rule 7.46(b) addresses the status of not-held and auction orders for purposes of Appendix B.I reporting. Currently, Appendix B.I sets forth eight categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. Currently, Appendix B.I does not provide a category for not held orders, clean cross orders, auction orders, or orders received when the NBBO is crossed. The Exchange and the other Participants have determined that it is appropriate to include separate categories for these orders types for purposes of Appendix B reporting. The Exchange is therefore proposing *Commentary* .50 to proposed Rule 7.46(b) to provide that not held orders shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (18). Clean cross orders shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (19); auction orders shall be included an as order type for purposes of Appendix B reporting, and shall be assigned the number (20); and orders that cannot otherwise be classified, including, for example, orders received when the NBBO is crossed shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (21). All of these orders already are included in the scope of Appendix B; however, without this proposed change, these order types would be categorized with other orders, such as regular held orders, that should be able to be fully executed upon receipt, which would compromise the value of this data.

The Exchange is proposing *Commentary* .60 to proposed Rule 7.46(b) to clarify the scope of the Plan as it relates to ETP Holders that only execute orders limited purposes. Specifically, The Exchange and the other Participants believe that an ETP Holder that only executes orders otherwise than on a national securities exchange for the purpose of: (1) Correcting a bona fide error related to the execution of a customer order; (2) purchasing a security from a customer at a nominal price solely for purposes of liquidating the customer's position; or (3) completing the fractional share portion of an order[32] shall not be deemed a Trading Center for purposes of Appendix B to the Plan. The Exchange is therefore proposing *Commentary* .60 to proposed Rule 7.46(b) to make this clarification.

The Exchange is proposing *Commentary* .70 to proposed Rule 7.46(b) to clarify that, for purposes of the Plan, Trading Centers must begin the data collection required pursuant to Appendix B.I.a(1) through B.II.(y) of the Plan and Item I of Appendix C of the Plan on April 4, 2016. While the Exchange or the ETP Holder's DEA will provide the information required by Appendix B and C of the Plan during the Pilot Period, the requirement thats [sic] the Exchange or their DEA provide information to the SEC within 30 days following month end and make such data publicly available on its Web site pursuant to Appendix B and C shall commence six months prior to the beginning of the Pilot Period.[33]

The Exchange is proposing *Commentary* .80 to proposed Rule 7.46(b) to address the requirement in Appendix C.I(b) of the Plan that the calculation of raw Market Maker realized trading profits utilize a last in, first out ("LIFO")-like method to determine which share prices shall be used in that calculation. The Exchange and the other Participants believe that it is more appropriate to utilize a methodology that yields LIFO-like results, rather than utilizing a LIFO-like method, and the Exchange is therefore proposing *Commentary* .80 to proposed Rule 7.46(b) to make this change.[34] The Exchange is proposing that, for purposes of Item I of Appendix C, the Participants shall calculate daily Market Maker realized profitability statistics for each trading day on a daily LIFO basis using reported trade price and shall include

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from 0 to less than 100 microseconds after the time of order receipt; and Appendix B.I.a(22) requires reporting of the cumulative number of shares of orders cancelled from 100 microseconds to less than 100 milliseconds after the time of order receipt.

[30] The Commission granted BZX an exemption from Rule 608(c) related to this provision. See Exemption Letter, *supra* note 27.

[31] The Commission granted BZX an exemption from Rule 608(c) related to this provision. See Exemption Letter, *supra* note 27.

[32] The Exchange notes that where an ETP Holder purchases a fractional share from a customer, the Trading Center that executes the remaining whole shares of that customer order would subject to subject to Appendix B of the Plan.

[33] In its order approving the Plan, the SEC noted that the Pilot shall be implemented within one year of the date of publication of its order, *e.g.*, by May 6, 2016. *See* Approval Order, 80 FR at 27545. However, on November 6, 2015, the SEC extended the implementation date approximately five months to October 3, 2016. *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (File No. 4–657) (Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program). *See also* Letter from Brendon J. Weiss, Co-Head, Government Affairs, Intercontinental Exchange/NYSE, to Brent J. Fields, Secretary, Commission, dated November 4, 2015 (requesting the data collection period be extended until six months after the requisite SRO rules are approved, and the implementation data of the Tick Size Pilot until six months thereafter).

[34] Appendix C.I currently requires Market Maker profitability statistics to include (1) the total number of shares of orders executed by the Market Maker; (2) raw Market Maker realized trading profits, which is the difference between the market value of Market Maker shares and the market value of Market Maker purchases, using a LIFO-like method; and (3) raw Market Maker unrealized trading profits, which is the difference between the purchase or sale price of the end-of-day inventory position of the Market Maker and the Closing Price. In the case of a short position, the Closing Price from the sale will be subtracted; in the case of a long position, the purchase price will be subtracted from the Closing Price.

only trades executed on the subject trading day. The daily LIFO calculation shall not include any positions carried over from previous trading days. For purposes of Item I.c of Appendix C, the Participants shall calculate daily Market Maker unrealized profitability statistics for each trading day on an average price basis. Specifically, the Participants must calculate the volume weighted average price of the excess (deficit) of buy volume over sell volume for the current trading day using reported trade price. The gain (loss) of the excess (deficit) of buy volume over sell volume shall be determined by using the volume weighted average price compared to the closing price of the security as reported by the primary listing exchange. In reporting unrealized trading profits, the Participant shall also report the number of excess (deficit) shares held by the Market Maker, the volume weighted average price of that excess (deficit) and the closing price of the security as reported by the primary listing exchange used in reporting unrealized profit.[35]

Finally, the Exchange is proposing *Commentary* .90 to proposed Rule 7.46(b) to address the securities that will be used for data collection purposes prior to the commencement of the Pilot Period. The Exchange and the other Participants have determined that it is appropriate to collect data for a group of securities that is larger, and using different quantitative thresholds, than the group of securities that will be Pilot Securities. The Exchange is therefore proposing *Commentary* .90 to proposed Rule 7.46(b) to define "Pre-Pilot Data Collection Securities" as the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C of the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Participants shall compile the list of Pre-Pilot Data Collection Securities by selecting all NMS stocks with a market capitalization of $5 billion or less, a Consolidated Average Daily Volume (CADV) of 2 million shares or less and a closing price of $1 per share or more. The market capitalization and the closing price thresholds shall be applied to the last day of the pre-pilot measurement period, and the CADV threshold shall be applied to the duration of the pre-pilot measurement period. The pre-pilot measurement period shall be the three calendar months ending on the day when the Pre-Pilot Data Collection Securities are selected. The Pre-Pilot Data Collection Securities shall be selected thirty days prior to the commencement of the six-month pre-pilot period. On the trading day that is the first trading day of the Pilot Period through six months after the end of the Pilot Period, the data collection requirements will become applicable to the Pilot Securities only. A Pilot Security will only be eligible to be included in a Test Group if it was a Pre-Pilot Data Collection Security.

Implementation Date

The proposed rule change will be effective on April 4, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[36] in general, and furthers the objectives of Section 6(b)(5) of the Act[37] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant of the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan and applies specific obligations to ETP Holders in furtherance of compliance with the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant of the Plan. The Exchange also notes that the data collection requirements for ETP Holders that operate Trading Centers will apply equally to all such ETP Holders, as will the data collection requirements for Market Makers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[38] and Rule 19b–4(f)(6) thereunder.[39]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[40] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[41] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it would allow the Exchange to implement the proposed amendments on April 4, 2016, the date upon which the data collection requirements of the Plan become effective.[42] Therefore, the Commission hereby waives the operative delay and designates the proposal operative on April 4, 2016.[43]

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[35] The Commission granted BZX an exemption from Rule 608(c) related to this provision. See Exemption Letter, *supra* note 27.

[36] 15 U.S.C. 78f(b).

[37] 15 U.S.C. 78f(b)(5).

[38] 15 U.S.C. 78s(b)(3)(A).

[39] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[40] 17 CFR 240.19b–4(f)(6).

[41] 17 CFR 240.19b–4(f)(6)(iii).

[42] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (File No. 4–657) (Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program).

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2016–52 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2016–52. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2016–52, and should be submitted on or before April 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[44]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07831 Filed 4–5–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77491; File No. SR–NYSE–2016–24]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 2, Amending Its Rules Relating to Pre-Opening Indications and Opening Procedures To Promote Greater Efficiency and Transparency at the Open of Trading on the Exchange

March 31, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 31, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rules relating to pre-opening indications and opening procedures to promote greater efficiency and transparency at the open of trading on the Exchange. This Amendment No. 2 supersedes the original filing in its entirety. The proposed rule change is available on the Exchange's Web site at *www.nyse.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules relating to pre-opening indications and opening procedures to promote greater efficiency and transparency at the open of trading on the Exchange. In particular, the Exchange proposes to:

- Make changes to the rules related to the pre-opening indication process by:
  - ○ Amending Rules 15 and 123D to consolidate the requirements for publication of pre-open indications in a single rule (Rule 15);
  - ○ changing the conditions in which a Designated Market Maker ("DMM") is required to publish a pre-opening indication in a security to an anticipated 5% move from a security's reference price and, during extreme market-wide volatility, an anticipated 10% from a security's reference price; and
  - ○ providing for the CEO of the Exchange to temporarily suspend the requirement to publish pre-opening indications.
- Make changes to Rule 123D related to the opening process by:
  - ○ Incorporating all procedures relating to openings, other than pre-opening indications, in Rule 123D; and
  - ○ Specifying that DMMs may effect an opening of a security electronically within specified percentage and volume parameters, which would be doubled during extreme market-wide volatility; and
  - ○ providing for the CEO of the Exchange to temporarily suspend price and volume limitations for a DMM

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[43] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[44] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

automated open or the requirement for prior Floor Approval before opening or reopening a security.

- Delete Rule 48
- Make conforming changes to Rules 80C, 124 and 9217.

The Exchange believes that the proposed changes will enhance transparency regarding the Exchange's opening process by specifying new parameters for how the opening at the Exchange would be effectuated on trading days experiencing extreme market-wide volatility, which would include both additional information before the open through the use of new parameters for pre-opening indications and expanded ability for DMMs to effectuate an opening electronically. The proposed rule changes are designed to preserve the Exchange's existing model, which values human touch when opening securities with significant price or volume disparity, while at the same time promoting automated measures to have as many securities open as close to 9:30 a.m. as feasible, even during extreme market-wide volatility.

Background

The Exchange's current pre-opening procedures are outlined in Rules 15 (Pre-Opening Indications), 48 (Exemptive Relief—Extreme Market Volatility Condition), and 123D (Openings and Halts in Trading).

Rule 15(a) provides that if the opening transaction in a security will be at a price that represents a change of more than the "applicable price change" specified in the Rule,[4] the DMM arranging the opening transaction or the Exchange shall issue a pre-opening indication ("Rule 15 Indication"), which represents a price range in which a security is anticipated to open.

A Rule 15 Indication is published on the Exchange's proprietary data feeds only and includes the security and the price range within which the DMM anticipates the opening transaction will occur, and would include any orally-represented Floor broker interest for the open. The applicable price ranges for determining whether to publish a Rule 15 Indication are based on five different price buckets and are expressed in dollar and percentage parameters:

Exchange closing price	Applicable price change (more than)
Under $20.00	$0.50
$20–$49.99	$1.00
$50.00–$99.99	$2.00
$100–$500	$5.00
Above $500	1.5%

Rule 123D also mandates that pre-opening indications be published if the opening price would result in a significant price change from the previous close or if the opening is delayed past 10:00 a.m. Eastern Time ("Rule 123D Mandatory Indication"). The DMM is responsible for publishing the Rule 123D Mandatory Indication and, when determining the price range for the indication, takes into consideration Floor broker interest that has been orally entered and what, at a given time, the DMM anticipates the dealer participation in the opening transaction would be. Rule 123D Mandatory Indications are published to the Consolidated Tape and proprietary data feeds. The applicable price ranges for determining whether an opening price would be a "significant" price change requiring a Rule 123D Mandatory Indication are based on three price buckets and are expressed in a mixture of dollar (1 point = one dollar) and percentage parameters:

Previous NYSE closing price	Price change (equal to or greater than)
Under $10.00	1 point.
$10—$99.99	the lesser of 10% or 3 points.
$100 and Over	5 points.

Rule 48 provides that a "qualified Exchange officer" [5] can invoke an extreme market volatility condition at the open (or reopen of trading following a market-wide halt of securities) during which time the Exchange can suspend the requirements of Rules 15 and 123D, and in particular, the requirement to publish pre-opening indications. Rule 48 is intended to be invoked only in those situations where the potential for extreme market volatility would likely impair Floor-wide operations at the Exchange by impeding the fair and orderly opening or reopening securities.[6]

Finally, Rule 123D, which in addition to setting forth requirements for certain pre-opening indications, also specifies procedures relating to openings, including that it is the responsibility of each DMM to ensure that securities open as close to the opening bell as possible and that securities can be opened on a trade or a quote. The rule further provides that openings may be effectuated manually or electronically.

Proposed Rule Change

The Exchange proposes to amend Rules 15, 48, and 123D to introduce greater efficiency and transparency into its opening process by, among other things, consolidating its rules regarding pre-opening indications into a single rule (Rule 15), introducing a new, single percentage parameter for the publication of pre-opening indications that would double on volatile trading days, and consolidating opening procedures into Rule 123D, including specifying parameters of when a DMM may effect an opening electronically, and consolidating the procedures of Rule 48 into Rules 15 and 123D, as applicable. The Exchange also proposes conforming changes to Rules 80C, 124 and 9217.

Pre-Opening Indications

The Exchange proposes to make changes to the pre-opening indication process. The Exchange would consolidate the requirements relating to pre-opening indications into Rule 15(a)–(f). Because the Exchange proposes all new rule text in Rule 15(a)–(f), the Exchange proposes to delete paragraphs (a) and (b) of current Rule 15, re-number Rule 15(c) as Rule 15(g), delete rule text in Rule 123D(b) relating to mandatory indications, and amend the title of Rule 15 to add the phrase "and Opening Order Imbalance Information" so that the rule would be titled "Pre-Opening Indications and Opening Order Imbalance Information." In amending Rule 15, the Exchange would establish new conditions for when DMMs are required to publish pre-opening indications.

Proposed Rule 15(a), entitled "Pre-Opening Indications," would provide that a pre-opening indication would include the security and the price range within which the opening price is anticipated to occur. This proposed rule text is based on the last clause of the first sentence of current Rule 15(a), which provides that a pre-opening indication includes the security and the price range within which the opening transaction is anticipated to occur. Proposed Rule 15(a) would further provide that a pre-opening indication would be published via the securities information processor ("SIP") and proprietary data feeds. This proposed rule text is based on the way in which Rule 123D Mandatory Indications are currently published to both the SIP and proprietary data feeds. The Exchange proposes to use the term "securities information processor" instead of "Consolidated Tape" to use the term more commonly used in the industry.[7]

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[4] In current Rule 15, other than for certain American Depositary Receipts ("ADRs"), the "applicable price change" is measured from a security's last reported sale price on the Exchange, the security's offering price in the case of an initial public offering ("IPO"), or the security's last reported sale price on the market from which it is being transferred. For an ADR where the trading day of the underlying security in the primary foreign market for the ADR concludes after the previous day's trading in the US has ended, the "applicable price change" is measured from closing price of the primary foreign market. For an ADR where the primary foreign market on which the underlying security is open for trading at the time of the opening of the Exchange, the "applicable price change" is measured from parity with the last sale price of the underlying security.

[5] A "qualified Exchange officer" means the Chief Executive Officer of ICE, or his or her designee, or the Chief Regulatory Officer of the Exchange, or his or her designee.

[6] *See* Securities Exchange Act Release No. 56920 (December 6, 2007), 72 FR 70915 (December 13, 2007) (SR–NYSE–2007–111) ("Rule 48 Notice of Filing").

Proposed Rule 15(b), entitled "Conditions for Publishing a Pre-Open Indication," would set forth the conditions in which a DMM is required to publish a pre-opening indication.

- Proposed Rule 15(b)(1) would provide that a DMM will publish a pre-opening indication before a security opens if the opening transaction on the Exchange is anticipated to be at a price that represents a change of more than the "Applicable Price Range," as defined in proposed Rule 15(d), from a specified "Reference Price," as defined in proposed Rule 15(c), before the security opens. The procedures for publishing a pre-opening indication would be described in Rule 15(e). This proposed rule text is based on current Rule 15(a), which uses the term "applicable price range" and describes the reference prices used for purposes of current Rule 15(a). The Exchange proposes to define the "Reference Price" and "Applicable Price Range" in proposed Rules 15(c) and (d), described below. The requirement for DMMs to publish pre-opening indications is based on current Rule 15(a), which provides that the DMM shall issue a pre-opening indication if the conditions set forth in the rule are met.
- Proposed Rule 15(b)(2) would specify that when making a determination of what the opening transaction price would be, the DMM will take into consideration all interest eligible to participate in the opening transaction, including electronically-entered orders, the DMM's own interest, and any interest represented orally in the crowd. This proposed rule text would be new and is designed to promote transparency in Exchange rules that all interest eligible to participate in the opening transaction is considered when publishing a pre-opening indication.
- Proposed Rule 15(b)(3) would provide that if a DMM is unable to publish a pre-opening indication for one or more securities due to a systems or technical issue, the Exchange may publish the pre-opening indication. This proposed rule text is based in part on current Rule 15(a), which provides that either the DMM or the Exchange shall publish a pre-opening indication. The Exchange proposes a substantive difference to provide that the Exchange "may" rather than "shall" publish a pre-opening indication. As set forth in current Rule 123D(a)(5), which was added after the applicable rule text in Rule 15(a),[8] if a DMM is unavailable to open a security and the Exchange opens trading, the Exchange will not publish a pre-opening indication. Because the Exchange is not obligated to publish pre-opening indications in such scenario, the Exchange proposes to make Rule 15(b)(3) consistent with that rule.

Proposed Rule 15(c), entitled "Reference Price," would provide in paragraph (1) that the Reference Price for a security (other than an American Depository Receipt ("ADR")) for purposes of the proposed rule would be:

- The security's last reported sale price on the Exchange (proposed Rule 15(c)(1)(A));
- in the case of an IPO, the security's offering price (proposed Rule 15(c)(1)(B)); or
- the security's last reported sale price on the securities market from which the security is being transferred to the Exchange, on the security's first day of trading on the Exchange (proposed Rule 15(c)(1)(C)).

This proposed rule text is based on current Rule 15(a).[9]

Proposed Rule 15(c)(2) would provide that the Reference Price for ADRs for purposes of the proposed rule would be:

- The closing price of the security underlying the ADR in the primary foreign market in such security when the trading day of the primary foreign market concludes (proposed Rule 15(c)(2)(A)); or
- based on parity with the last sale price of the security underlying the ADR in the primary foreign market for such security when the trading day of the primary foreign market is open for trading at the time of the opening on the Exchange (proposed Rule 15(c)(2)(B)).

This proposed rule text is based on current Rule 15(b), with non-substantive differences for clarity and to use the defined term "Reference Price" in the proposed rule text.[10] Proposed Rule 15(c)(3) would further provide that the Reference Price for reopening a security following a halt would be the security's last reported sale price on the Exchange. The Exchange proposes to specify the Reference Price for reopening following a halt because the Reference Price would be the same for all securities, including ADRs, which would be trading on the Exchange.

Proposed Rule 15(d) would set forth the Applicable Price Ranges for determining whether a DMM is required to disseminate a pre-opening indication. The Exchange proposes to eliminate the current price buckets in Rules 15 and 123D and instead use a single percentage parameter as the Applicable Price Range for all securities, regardless of price of the security. As proposed, except during extreme market-wide volatility as set forth in proposed Rule 15(d)(2), a DMM would be required to publish a pre-opening indication if a security is expected to open at a price more than 5% away from the Reference Price. The Exchange believes that the proposed 5% parameter applicable to all securities would simplify and streamline the Exchange's rules regarding required pre-opening indications by having a single percentage parameter that would be applied across all securities, rather than having different price buckets and percentage parameter ranges to track. The Exchange further believes that the proposed single percentage parameter would result in a similar number of pre-opening indications as are currently published pursuant to Rule 123D, while at the same time simplifying the process for DMMs.

For example, using trade data for the month of October 2015, which was a month of relative trading stability and volumes, current Rule 123D Mandatory Indication parameters required indications for 15 securities on an average daily basis, which represents approximately 0.46% of the securities traded on the Exchange. Applying the proposed new percentage parameter of 5% to the same October 2015 trade data, DMMs would have been required, on average, to publish 33 pre-opening indications, which represents 1.01% of securities that trade on the Exchange. The Exchange believes that the incremental increase in number of pre-opening indications that would have been published pursuant to the proposed new single percentage parameter would promote transparency in the opening of securities at the Exchange.[11]

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[7] *See, e.g.,* Supplementary Material .01 to Rule 19.

[8] *See* Securities Exchange Act Release No. 76290 (Oct. 28, 2015), 80 FR 67822 (Nov. 3, 2015) (SR–NYSE–2015–49).

[9] *See supra* note 4.

[10] The seventh paragraph of Rule 123D(b), which the Exchange proposes to delete, similarly describes the reference price to be used for a foreign-listed security.

Under current rules, the Exchange may suspend the requirement to publish pre-opening indications if a market-wide extreme market volatility condition is declared under Rule 48. This rule was adopted, in part, because of the manual nature of publishing pre-opening indications, and if DMMs were required to publish Rule 123D Mandatory Indications for multiple securities, it could delay the opening process and result in a large number of securities opening past 9:30 a.m. Eastern Time.[12] Historically, the Exchange has declared such a condition if, before the opening of trading, the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures. However, based on the events of the week of August 24, 2015, when the Exchange declared extreme market volatility conditions on August 24, 25, and 26, the Exchange appreciates that the absence of any pre-opening indications may leave a void in the information available for market participants to assess the price at which a security may open. Yet, because market-wide volatility would cause the price of most or all securities to move significantly away from the last sale price on the Exchange, the Exchange believes that the 5% price move appropriate for "normal" trading days would result in a DMM being required to disseminate more pre-opening indications than is feasible.

Accordingly, the Exchange proposes to amend its rules to provide that on trading days with extreme market-wide volatility, the Applicable Price Range would be 10%, or double the Applicable Price Range on regular trading days. Specifically, proposed Rule 15(d)(2) would provide that, if as of 9:00 a.m. Eastern Time ("ET"), the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures, when reopening trading following a market-wide trading halt under Rule 80B, or if the Exchange determines that it is necessary or appropriate for the maintenance of a fair and order market, a DMM would be required to publish a pre-opening indication in a security if the price of that security is expected to open at a price more than 10% away from the Reference Price. By proposing to specify the conditions in which the Applicable Price Range would be 10%, the Exchange would promote transparency in Exchange rules so that market participants will know when the double-wide percentage parameter would be applied. Because the standard for extreme market-wide volatility would be specified in the rule, the Exchange would not need to provide separate notification on a trading day when the double-wide percentages would be applicable.

By proposing to specify in its rules that the Applicable Price Range would be 10%, rather than 5%, when the market is more volatile, the Exchange would require DMMs to disseminate pre-opening indications in those securities experiencing the greatest price movement. Under current rules, the Exchange's only option when the overall market is volatile is to lift the requirement for pre-opening indications under Rule 48. The Exchange also proposes to use the 10% percentage parameter when reopening securities following a market-wide trading halt under Rule 80B. The Exchange believes that widening the parameters for pre-opening indications following a market-wide trading halt would be appropriate because the reason for the trading halt was market-wide volatility, and thus the reopening of securities would face similar pricing pressure as circumstances when there is pre-opening extreme market-wide volatility. The Exchange also proposes that it would have the authority to use the 10% Applicable Price Range when it is necessary or appropriate for the maintenance of a fair and orderly market. For example, if the E-mini S&P 500 Futures were not plus or minus 2% as of 9:00 a.m., but moved to that level between 9:00 and 9:30, it may be appropriate, for the maintenance of a fair and orderly market, to use widened percentage parameters.

To determine the percentage parameter that would be appropriate for trading days with extreme market-wide volatility, the Exchange reviewed trading data from August 24, 25, and 26, 2015 and assessed how many Rule 123D Mandatory Indications would have been required under current rules, and how many pre-opening indications would have been required if a 5% and 10% percentage parameter were used on those days. Taking for example August 24, 2015, as set forth on Table 1 below, the data show that, had the Exchange not invoked Rule 48 lifting the requirement to publish Rule 123D Mandatory Indications, there would have been 638 securities (19% of securities) for which DMMs would have been required to publish Rule 123D Mandatory Indications. As set forth in Table 2 below, a 5% percentage parameter would have required 1,460 pre-opening indications (44% of securities) on August 24, 2015, more than twice as many as under the current parameters. As noted above, the Exchange believes that this would be too many pre-opening indications for DMMs to process on a trading day without impacting their ability to timely open their assigned securities.

By contrast, as set forth in Table 2 below, a 10% percentage parameter would have required pre-opening indications in 278 securities (8.4% of securities) on August 24, 2015. While this number is still higher than the number of pre-opening indications that would have been published on an average trading day in October using the 5% percentage parameter (see above), the Exchange believes that it strikes the appropriate balance between providing additional pre-opening information to investors and enabling the DMM's to timely open their assigned securities. As set forth in more detail in Tables 1 and 2 below, August 24 represents an outlier, even for days when there has been extreme market-wide volatility. For other days in 2015 when the Exchange declared an extreme market-wide volatility under Rule 48, as set forth in Tables 1 and 2 below, applying a 10% parameter would not materially change the number of pre-opening indications being published.

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[11] For purposes of this analysis, the Exchange compared the proposed new percentage parameters against only the current Rule 123D Mandatory Indications because these indications are more widely distributed via the SIP to market participants, and therefore more likely to be relied upon for purposes of assessing the opening price of a security on the Exchange. In addition, unlike Rule 15 Indications, a DMM is required to update Rule 123D Mandatory Indications, and thus this form of pre-opening indication is more likely to track to the actual opening price of a security.

[12] *See* Rule 48 Notice of Filing, *supra* note 6 at 70916.

Table 1: Current Rule 123D Mandatory Indication Parameters

		October 2015 (Average)			8/24/2015			8/25/2015			8/26/2015			1/27/2015		
Exchange Closing Price	Applicable Price Change (More Than)	Total # of Stocks	# Stocks over Price or Volume Parameter	% Over Total	Total # of Stocks	# Stocks over Price or Volume Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total
Under $10.00	$1	3284	2	0.06%	3293	17	0.52%	3293	2	0.06%	3294	4	0.12%	3295	0	0.00%
$10.00-$99.99	Lessor of 10% or $3	3284	7	0.21%	3293	499	15.15%	3293	48	1.46%	3294	15	0.46%	3295	4	0.12%
$100 or greater	$5	3284	6	0.18%	3293	122	3.70%	3293	31	0.94%	3294	20	0.61%	3295	8	0.24%
Total			15	0.46%		638	19.37%		81	2.46%		39	1.18%		12	0.36%

Table 2: Required Pre-Opening Indications with 5% and 10% Applicable Price Range

		October 2015 (Average)			8/24/2015			8/25/2015			8/26/2015			1/27/2015		
Exchange Closing Price	Applicable Price Change (More Than)	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total	Total # of Stocks	# Stocks over Price Parameter	% Over Total
If S&P 500 e-Mini Futures Change Less Than +/-2%	5%	3283	33	1.01%	3293	1460	44.34%	3293	255	7.74%	3294	67	2.03%	3295	17	0.52%
If S&P 500 e-Mini Futures Change Greater Than +/-2%	10%	3283	8	0.24%	3293	278	8.44%	3293	51	1.55%	3294	18	0.55%	3295	2	0.00%

Proposed Rule 15(e), entitled "Procedures for publishing a pre-opening indication," would set forth proposed procedures a DMM would use when publishing a pre-opening indication. As discussed below, these procedures are based on existing procedures currently set forth in Rule 123D, with specified differences.

Proposed Rule 15(e)(1) would provide that publication of pre-opening indications requires the supervision and approval of a Floor Governor.[13] This proposed rule change is based on the sixth paragraph of Rule 123D(b). The Exchange proposes a substantive change in that the proposed rule would require the supervision and approval of a Floor Governor, rather than supervision and approval of a Floor Official, as set forth in the current rule. The Exchange would also eliminate the requirement in Rule 123D that if a situation involves a bank or brokerage stock, the approval of an Executive Floor Governor is required, and if an Executive Floor Governor is unavailable, a Floor Governor or Senior Floor Governor's approval is required. The Exchange believes that requiring Floor Governor approval for all securities would involve the appropriate review by an experienced Floor official, while at the same time simplifying the approval process to require a single category of Floor Official to approve a pre-opening indication regardless of the type of security.[14]

Proposed Rule 15(e)(2) would provide that a pre-opening indication must be updated if the opening transaction would be at a price outside of a published pre-opening indication. Proposed Rule 15(e)(3) would further require that if a pre-opening indication is a spread wider than $1.00, the DMM should undertake best efforts to publish an updated pre-opening indication of $1.00 or less before opening the security, as may be appropriate for the specific security. Proposed Rules 15(e)(2) and (e)(3) are based, in part, on the second and third bullet points following the ninth paragraph of Rule 123D(b),[15] but with new rule text to simplify the requirements regarding updating pre-opening indications. With respect to proposed Rule 15(e)(3), for higher-priced securities, a pre-opening indication wider than $1.00 may be appropriate and it may not be necessary to narrow such indication any further, particularly since Opening Imbalance Information pursuant to Rule 15(c) (proposed Rule 15(g)) would also be disseminated regarding the security.

Proposed Rule 15(e)(4) would provide that, after publication of a pre-opening indication, the DMM must wait for the following minimum specified periods before opening a security:

- Proposed Rule 15(e)(4)(A) would provide that, when using the 5% Applicable Price Range specified in proposed Rule 15(d)(1), a minimum of three minutes must elapse between publication of the first indication and a security's opening. The rule would further provide that, if more than one indication has been published, a security may be opened one minute after the last published indication provided that at least three minutes have elapsed from the dissemination of the first indication. These first two sentences of proposed Rule 15(e)(4)(A) are based on rule text set forth in the twelfth and thirteenth paragraphs of current Rule 123D(b). Proposed Rule 15(e)(4)(A) would further provide that the DMM may open a security less than the required wait times after the publication of a pre-opening indication if the imbalance is paired off at a price within the Applicable Price Range. This proposed exception to the three-minute waiting requirement is new and is because the Exchange believes that, if equilibrium in price has been reached at a price within the Applicable Price Range, *i.e.*, at a price that would not have required a pre-opening indication in the first instance, there is no reason to require the DMM to further delay the opening of the security in an effort to attract offsetting interest.
- Proposed Rule 15(e)(4)(B) would provide that, when using the 10% Applicable Price Range specified in Proposed Rule 15(d)(2), a minimum of one minute must elapse between publication of the first indication and a security's opening and that if more than one indication has been published, a security may be opened without waiting any additional time. As discussed above, proposed Rule 15(d)(2) would provide for new percentage parameters for trading days with extreme market-wide volatility. Based on the analysis of trade data for August 24, 2015, even with the new percentage parameters, there is the potential for 278 pre-opening indications to be required on an extremely volatile trading day. Because these pre-opening indications would be manually published by the DMM, the Exchange believes that eliminating additional wait times would enable the

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[13] Rule 46 describes the different categories of Floor Officials, which are Floor Officials, Senior Floor Officials, Executive Floor Officials, Floor Governors, and Executive Floor Governors. Floor Governors are generally more senior members of the Trading Floor or qualified Exchange employees and are also empowered to perform any duty of a Floor Official.

[14] The Exchange would also be deleting the 14th through 16th paragraphs of Rule 123D(b) regarding Floor Official approval for "tape indications," which are Rule 123D Mandatory Indications. The Exchange believes that proposed Rule 15(e)(1) simplifies the approval process and obviates the need for this Rule 123D rule text.

[15] The second bullet following the ninth paragraph of Rule 123D(b) requires that the number of indications should increase in proportion to the anticipated disparity in the opening or reopening price, with increasingly definitive, "telescoped" indications when an initial narrow indication spread is impractical. The third bullet provides for similar requirements following a non-regulatory halt, and specifically that a final indication with a one point (one dollar) spread would be appropriate.

DMMs to facilitate a speedy opening for a security that has been subject to a pre-opening indication on days with extreme market-wide volatility.

Proposed Rule 15(e)(5) would provide that, if trading is halted for a non-regulatory order imbalance, a pre-opening indication must be published as soon as practicable after the security is halted. This proposed rule text is based on the first sentence of the third bulleted paragraph following the ninth paragraph in Rule 123D(b), with a proposed substantive difference that a pre-opening indication should be published "as soon as practicable," rather than "immediately," after a security is halted. The Exchange believes that the proposed approach provides for more flexibility for the DMM to assess the order imbalance and publish a pre-opening indication that takes into consideration all applicable factors.

Proposed Rule 15(e)(6) would set forth the requirements for pre-opening indications when reopening a security following a trading pause under Rule 80C.[16] Proposed Rule 15(e)(6)(A) would provide that a pre-opening indication may be published without prior Floor Governor approval. Proposed Rule 15(e)(6)(B) would provide that a pre-opening indication would not need to be updated before reopening the security, and the security may be reopened outside of any prior indication. Lastly, proposed Rule15(e)(6)(C) would provide that the reopening is not subject to the minimum waiting time requirements in Proposed Rule 15(e)(4). Proposed Rules 15(e)(6)(A)–(C) are based on Rule 80C(b)(2)(A), with non-substantive differences to use different rule text cross-references.

Proposed Rule 15(f), entitled "Temporary Suspension of Pre-Opening Indications," would provide in proposed Rule 15(f)(1) that if the CEO of the Exchange determines that a Floor-wide event is likely to impact the ability of DMMs to arrange for a fair and orderly opening or reopening and that absent such relief, operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend the requirement to publish pre-opening indications under Rule 15 prior to opening or reopening a security following a market-wide trading halt.[17]

Proposed Rule 15(f) is based in part on Rule 48, which provides that a qualified Exchange officer may declare an extreme market volatility condition and temporarily suspend the requirements for pre-opening indications.[18] Because the Exchange would be specifying new percentage parameters for pre-opening indications on trading days with market-wide volatility, the Exchange does not believe that it needs Rule 48 in its current form. While the Exchange expects that its other proposed changes to DMMs' requirements related to pre-opening indications will make it unlikely that a complete suspension of pre-opening indications would be required, the Exchange believes it would be prudent for the CEO of the Exchange to retain the authority to temporarily suspend the requirements to make pre-opening indications for events that it cannot currently predict. Accordingly, rather than refer to extreme market-wide volatility as in current Rule 48, proposed Rule 15(f)(1) would refer to a Floor-wide event that could impact the fair and orderly opening or reopening of securities more generally.

Proposed Rule 15(f)(2), which is based on Rule 48(c)(1)(A), would specify the range of factors that the CEO of the Exchange would be required to consider in making any determination to temporarily suspend the requirement for pre-opening indications.[19] In addition, similar to Rule 48(c)(1)(B) and 48(c)(1)(C), proposed Rules 15(f)(2)(B) and (C) would require the CEO to consult with the CRO of the Exchange in making a determination under proposed Rule 15(f)(1) and inform Commission staff as promptly as practicable that pre-opening indications under Rule 15 have been temporarily suspended. Proposed Rule 15(f)(3), which is based on Rule 48(c)(4), would provide that a temporary suspension under Rule 15(f) would be in effect only for the trading day on which it was declared.[20] Finally, proposed Rule 15(f)(4) would provide that notwithstanding a temporary suspension of the requirement to publish pre-opening indications in a security under Rule 15, a DMM or the Exchange may publish a pre-opening indication for one or more securities. This proposed rule text, which is based in part on Rule 48(c)(5), would allow a DMM or the Exchange to publish a pre-opening indication, even if the rule were suspended.[21] Unlike Rule 48(c)(5), which specifies conditions when the DMM should still publish a pre-opening indication, proposed Rule 15(f)(3) would not require pre-opening indications, but rather, would allow them to be published even if the rule were temporarily suspended.

Because the Exchange has added new subsections to Rule 15, the Exchange proposes to renumber Rule 15(c) as Rule 15(g) and to add a header to this subsection of rule entitled "Opening Order Imbalance Information." In addition to re-designating the rule from Rule 15(c) to Rule 15(g), the Exchange proposes non-substantive differences to re-number the subsections of proposed Rule 15(g) to use the same numbering convention as proposed for proposed Rule 15(a)–(f), delete the phrase "the provisions of" in proposed Rule 15(g)(2)(B), and remove the reference to subparagraph (b) by deleting the phrase "or (b)."

The Exchange also proposes a substantive difference to change Rule 15(c)(3)(iii) (re-numbered as proposed Rule 15(g)(3)(C)) to increase the frequency with which the Exchange disseminates Order Imbalance Information [22] beginning at 9:20 a.m.

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[16] Rule 80C sets forth the Exchange's rules to comply with the requirements of the Plan to Address Extraordinary Market Volatility submitted to the Commission pursuant to Rule 608 of Regulation NMS under the Act known as the Limit Up/Limit Down ("LULD") Plan.

[17] Pursuant to Rule 1, the CEO of the Exchange may formally designate one or more qualified employees of Intercontinental Exchange, Inc. ("ICE") to act in place of any person named in a rule as having authority to act under such rule in the event the named person in the rule is unavailable to administer that rule.

[18] Rule 48(d) defines a "qualified Exchange officer" for purposes of Rule 48 as the CEO of ICE, or his or her designee, or the Chief Regulatory Officer ("CRO") of the Exchange, or his or her designee. The Exchange proposes to streamline its rules to specify that only the CEO of the Exchange would have the authority to temporarily suspend the requirement for pre-opening indications. However, pursuant to Rule 1, the CEO could delegate this authority to other qualified ICE employees.

[19] As provided for in Rule 48(c)(1)(A), these factors include volatility in the previous day's trading session, trading in foreign markets before the open, substantial activity in the futures market before the open, the volume of pre-opening indications of interest, evidence of pre-opening significant order imbalances across the market, government announcements, news and corporate events, and such other market conditions that could impact Floor-wide trading conditions.

[20] Rule 48(c)(4) provides that that a declaration of an extreme market volatility condition under Rule 48 shall be in effect only for the particular opening or reopen for the trading session on the particular day that the extreme market volatility condition if determined to exist.

[21] Rule 48(c)(5) provides that a declaration of an extreme market volatility condition shall not relieve DMMs from the obligation to make pre-opening indications in situations where the opening of a security is delayed for reasons unrelated to the extreme market volatility condition.

[22] Order Imbalance Information reflects real-time order imbalances that accumulate prior to the opening transaction on the Exchange and the price at which interest eligible to participate in the opening transaction may be executed in full. Order Imbalance Information disseminated pursuant to Rule 15(c) includes all interest eligible for execution in the opening transaction of the security in Exchange systems, *i.e.,* electronic interest, including Floor broker electronic interest, entered into Exchange systems prior to the opening. Order

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ET. Currently, under Rule 15(c)(3)(iii), Order Imbalance Information is disseminated approximately every 15 seconds between 9:20 a.m. ET and the opening of trading in that security. The Exchange proposes to disseminate Order Imbalance Information approximately every 5 seconds between 9:20 a.m. ET and the opening of trading in that security. The Exchange believes that increasing the frequency with which Order Imbalance Information is disseminated would provide market participants with additional updated pre-opening information, thus promoting transparency for the opening transaction.

Finally, the Exchange proposes to add new Supplementary Material .10 to Rule 15 providing that, unless otherwise specified in the proposed Rule,[23] references to an opening transaction include a reopening transaction following a trading halt or pause in a security. Currently, Rule 123D Mandatory Indications are required for both openings and reopenings. Because proposed Rule 15 indications would similarly be required for openings and reopenings following a halt or pause, the Exchange proposes to add Supplementary Material .10 to Rule 15.

DMM Automated Openings

As noted above, the process for publishing either Rule 15 Indications or Rule 123D Mandatory Indications is manual, and is generally followed by the DMM effecting the opening of a security manually rather than electronically. Consistent with this approach, the Exchange currently systemically blocks DMMs from opening a security electronically if the opening price would be outside of price parameters that are based on the price buckets and applicable price ranges specified in Rule 15(a). The Exchange similarly blocks DMMs from electronically opening a security if size of the opening transaction would be a significant volume, which similarly would indicate the potential need for manual oversight of the opening process.

Because the DMM is not obligated to open a security electronically, the Exchange has not historically specified in its rules the parameters for when the DMM may effect an opening electronically.[24] However, following the events of the week of August 24, 2015, the Exchange believes that specifying in Exchange rules the conditions in which a DMM is permitted to open a security electronically would provide greater transparency in Exchange rules. The Exchange therefore proposes to amend Rule 123D(a) to specify when a DMM may effect an opening electronically.

In specifying parameters for when a DMM may effectuate an opening electronically, the Exchange proposes to adopt parameters and requirements that would be structured similarly to the proposed parameters for new Rule 15 pre-opening indications, as discussed above. To effect this change, the Exchange proposes new subsection numbering to Rule 123D(a)(1) to break out the third and fourth sentences of current Rule 123D(a)(1) to be proposed Rules 123D(a)(1)(A) and (B).[25] The Exchange proposes to add to proposed Rule 123D(a)(1)(B) that Exchange systems would not permit a DMM to open a security electronically if a DMM has manually entered Floor interest. This is how Exchange systems currently function and is similar to Rule 123C.10 regarding when a DMM may close a security electronically.

The Exchange proposes to set forth the parameters for when a DMM may effect an opening electronically in new proposed Rules 123D(a)(1)(B)(i) and (ii):

- Proposed Rule 123D(a)(1)(B)(i) would provide that except under the conditions set forth in Rule 123D(a)(1)(B)(ii), a DMM may not effect an opening electronically if the opening transaction would be at a price more than 4% away from the Official Closing Price, as defined in Rule 123C(1)(e), or the matched volume for the opening transaction would be more than (a) 150,000 shares for securities with an average opening volume of 100,000 shares or fewer in the previous calendar quarter; or (b) 500,000 shares for securities with an average opening volume of over 100,000 shares in the previous calendar quarter. For purposes of this Rule, the calendar quarters will be based on a January 1 to December 31 calendar year.
- Proposed Rule 123D(a)(1)(B)(ii) would provide that if as of 9:00 a.m. ET, the E-mini S&P 500 Futures are plus or minus 2% from the prior day's closing price of the E-mini S&P 500 Futures, or if the Exchange determines that it is necessary or appropriate for the maintenance of a fair and order market, a DMM could effect an opening electronically if the opening transaction would be at a price of up to 8% away from the Official Closing Price, as defined in Proposed Rule 123C(1)(e), without any volume limitations.

Similar to the new Applicable Price Ranges for pre-opening indications proposed in Rule 15(d) above, the Exchange proposes to use a single percentage parameter for all securities, regardless of price. The Exchange also proposes to double those percentage parameters on days with extreme market-wide volatility, and would use the same standard for determining whether there is market-wide volatility as is proposed in Rule 15(d)(2), described above. Because the Exchange continues to believe that, if a pre-opening indication has been published, a security is better served if a DMM effects a manual opening, the Exchange proposes to apply percentage parameters to DMM automated openings that are tighter than the requirements for publishing a pre-opening indication. In other words, if a pre-opening indication would be required under proposed Rule 15, the DMM would not be permitted to effect an opening electronically. To achieve this goal, the Exchange proposes that the percentage parameter on a regular trading day for DMM automated opens should be one percent lower than the percentage parameter for pre-opening indications on a regular trading day. And as with pre-opening indications, on a day with extreme market-wide volatility, the applicable percentage would be doubled.

The Exchange believes that the proposed conditions for when a DMM may effect an opening electronically would reduce the number of manual openings and enable more securities to open closer to 9:30 a.m. ET, both on regular trading days and on extremely volatile trading days such as August 24, 2015.

Tables 3 through 5 below illustrate how many securities would not be eligible for a DMM to effect an opening electronically when applying the current and proposed percentage and volume parameters to trade data from October 2015 and trade data from August 24, 2015.

Imbalance Information is disseminated on the Exchange's proprietary data feeds. *See* Rule 15(c)(1).

[23] *See, e.g.,* proposed Rules 15(d)(2) (referring only to reopenings following a market-wide trading halt under Rule 80B) and 15(e)(6) (specifying different procedures when reopening trading following a trading pause).

[24] Rule 123D does not require DMMs to open a security electronically; a DMM may determine that in the particular circumstances for a security, manually opening the security may be warranted, even if the price would be within the Applicable Price Range. For example, if a Floor broker has represented an order in the Crowd, the DMM will open a security manually.

[25] The Exchange also proposes a non-substantive amendment to change the term "stock" to "security."

Table 3: Automated Open - Current Price and Volume Parameters

			October 2015 (Average)					8/24/15				
Exchange Closing Price	Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter
Under $20.00	100K	$0.50	1228	29	2.4%	9	21	1300	546	42.0%	506	95
$20-$49.99	100K	$1.00	991	30	3.0%	13	19	1139	649	57.0%	646	67
$50.00-$320.00	100K	$2.00	534	35	6.6%	17	19	560	486	86.8%	486	70
Above $320.00	100K	1.50%	1	0	0.0%	0	0	1	1	100.0%	1	0
Total			2754	94	3.4%	39	59	3000	1682	56.1%	1639	232

Table 4: Automated Open - New Price % and Volume Parameters

			October 2015 (Average)					8/24/15				
Average Opening Volume in Previous Calendar Quarter	Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total	# Stocks over Price Parameter	# Stocks over Volume Parameter
100,000 shares or less	150,000+ shares	4.00%	2680	41	1.5%	36	8	2924	1682	57.5%	1671	86
Over 100,000 shares	500,000+ shares	4.00%	74	6	8.1%	3	3	76	71	93.4%	71	33
		Total	2754	47	1.7%	39	11	3000	1753	58.4%	1742	119

Table 5: Automated Open - New Double Wide Price % if S&P 500 e-Mini Futures Change +/-2% From Prior Day's Close

		October 2015 (Average)			8/24/2015		
Volume Parameter	Applicable Price Change (More Than)	Total # of Stocks Opening on Trade	# Stocks over Price Parameter	% Over Total	Total # of Stocks Opening on Trade	# Stocks over Price or Volume Parameter	% Over Total
none	8%	2754	11	0.4%	3000	573	19.1%

For example, as set forth in Table 3, using current price parameters and a 100,000 share volume parameter, in October 2015, 94 securities (13.4% of securities) on average each day were not eligible to be opened by the DMM electronically. As demonstrated in Table 4, using the proposed 4% price and tiered volume parameters, a comparable 47 securities (1.7% of securities) on average in October would not have been eligible to be opened by the DMM electronically.

With respect to the proposed volume parameters, the Exchange believes that having a parameter tied to higher-than-average opening volume in a security would better reflect whether opening electronically would be appropriate. For example, as the data show in Table 4, there were 74 securities averaging daily opening volume over 100,000 shares in the previous quarter (3Q15) and three of those securities had opening volume of over 500,000 shares on an average daily basis in October. The Exchange believes that if a security has a higher-than-average opening volume on a quarterly basis without any corresponding price dislocation, then the volume of shares trading on the opening for such securities is not representative of any volatility for that security, but rather, is a regular state of affairs that does not require a high-touch opening managed by a DMM on the trading Floor. Rather, such securities would benefit from being available for the DMM to open electronically in order to promote a fair and orderly opening at or near the open of trading.

As with pre-opening indications, the Exchange proposes to double the percentage parameter on trading days with extreme market-wide volatility and eliminate the volume parameter. As illustrated in Table 5, doubling the percentage parameter and eliminating the volume parameters would allow DMMs to open most securities electronically even during extreme market-wide volatility. As trade data from August 24, 2015 set forth in Table 3 illustrates, the current percentage parameters restricted DMMs from opening 1,753 securities electronically, which represents 58.4% of securities.[26] As set forth in Table 5, applying the proposed 8% percentage parameter would have allowed DMMs to open all but 573 securities electronically, which represents 19.1% of the securities traded on the Exchange.

The Exchange also proposes to add a new paragraph (c) to Rule 123D entitled "Temporary Suspension of DMM Automated Opening Limitations or Floor Official Approval." Similar to proposed Rule 15(f), if the CEO of the Exchange determines that a Floor-wide event it likely to have an impact on the ability of DMMs to arrange for a fair and orderly opening or reopening following a market-wide trading halt at the Exchange and that, absent relief, the operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend the prohibition on a DMM opening a security electronically if the opening transaction would be more than the price or volume parameters specified in proposed Rule 123D(a)(1)(B). This would be a new suspension authority that relates to the proposed new price and volume parameters for when a DMM may open a security electronically. The Exchange believes that having this temporary suspension authority would be appropriate for situations if the DMM is unable to open a security manually, either due to unavailability of 11 Wall Street facilities or because of systems or technical issues with Floor-based tools for manually opening a security.

Proposed Rule 123D(c) would also provide that if the CEO of the Exchange determines that a Floor-wide event is likely to have an impact on the ability of DMMs to arrange for a fair and orderly opening or reopening following a market-wide trading halt at the Exchange, and that absent relief, the operation of the Exchange is likely to be impaired, the CEO of the Exchange may temporarily suspend (i) the prohibition on a DMM opening a security electronically if the opening transaction will be more than the price or volume parameters specified in proposed Rule 123D(a)(1)(B); or (ii) the need under Rule 123D(b) for prior Floor Official approval to open or reopen a security following a market-wide trading halt. This proposed rule change is similar to authority in current Rule 48, which permits a qualified Exchange officer to temporarily suspend the need for prior Floor Official or prior NYSE Floor operations approval to open or reopen a security following a market-wide trading halt. While the Exchange expects that its other proposed changes to Rule 123D would make it unlikely that a complete suspension of prior Floor Official approval would be required, the Exchange believes it would be prudent for the CEO of the Exchange to retain the authority temporarily suspend such requirements for events that it cannot currently predict. The Exchange also proposes a new temporary suspension that correlates to the proposed new price and volume parameters for when a DMM may open a security electronically. The Exchange expects that this relief would be required if 11 Wall Street facilities were unavailable and DMMs would be required to open all securities remotely, and thus electronically.

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[26] On August 24, 2015, DMMs also chose not to open securities electronically, even if they would have been priced within the current price parameters.

Proposed Rule 123D(c)(2)–(3) are nearly identical to proposed Rule 15(f)(1)–(3), as described in greater detail above, with changes only to address that this proposed rule relates to the temporary suspension of the requirements for specified paragraphs of Rule 123D. Proposed Rule 123D(c)(2)–(3) is based on the same provisions of Rule 48 that proposed Rule 15(f)(2)–(4) is based on, which is discussed in greater detail above.

The miscellaneous and technical amendments proposed to Rule 123D are as follows:

- The Exchange proposes to amend Rule 123D(a)(5) (Pre-Opening Information) to change the citation to Rule 15(c) to 15(g) based on the proposed changes to Rule 15, described above, and delete the word "either" and the references to Rule 123D.
- The Exchange proposes to delete the phrase "Halts in Trading" from the heading of Rule 123D(b).
- Also in Rule 123D(b), the Exchange proposes to delete the text relating to the dissemination of mandatory indications beginning with the sentence "If an unusual situation exists, such as a large order imbalance, tape indications should be disseminated, including multiple indications if appropriate with the supervision of a Floor Official" through and including the sentence "An Executive Floor Governor or Floor Governor should be consulted in any case where there is not complete agreement among the Floor Officials participating in the discussion." This rule text all pertains to Rule 123D Mandatory indications, which, as discussed above, would be governed by proposed Rule 15.
- The Exchange proposes to add a new heading (c) entitled "Halts in Trading" before the sentence "Once trading has commenced, trading may only be halted with the approval of a Floor Governor or two Floor Officials" in current Rule 123D(b) and change current headings (c) (Equipment Changeover) and (d) of Rule 123D to (d) and (e), respectively.
- Finally, in current Rule 123D(c) (Proposed Rule 123D(e)), to reflect that all information relating to pre-opening indications, including the Applicable Price Ranges and Reference Prices, are now described in Rule 15, the Exchange proposes to delete the phrase "a significant order imbalance (one which would result in a price change from the last sale of one point or more for stocks under $10, the lesser of 10% or three points for $10—$99.99 and five points if $100 or more—unless a Floor Governor deems circumstances warrant a lower parameter) develops" and add the phrase "a pre-opening indication would be required to be published" in its place.

Rule 48

The Exchange proposes to delete Rule 48 in its entirety. As discussed above, the Exchange is proposing changes to Rules 15 and 123D that it believes will allow DMMs to publish pre-opening indications in a manageable number of securities, even on days of high volatility, which would promote transparency regarding opening prices at the Exchange. In addition, and as described above, the Exchange is incorporating into Rules 15 and 123D authority for the CEO of the Exchange to temporarily suspend the requirement to publish pre-opening indications, the pricing and volume limitations for a DMM to open a security electronically, and for a DMM to obtain Floor Official approval under Rule 123D(b) when opening or reopening a security, if the CEO of the Exchange determines that such relief is necessary to the ability of DMMs to open the securities and to the operation of the Exchange. Accordingly, the Exchange believes that the Rule 48 is no longer necessary.

Conforming and Technical Amendments—Rules 80C, 124 and 9217

Rule 80C

The Exchange proposes conforming amendments Rule 80C(b)(2), which governs a Trading Pause under the LULD Plan.

First, Rule 80C(b)(2) requires that the Exchange re-open the security in a manner similar to the procedures set forth in Rule 123D following a Trading Pause (as defined therein). The Exchange proposes to add a reference to Rule 15 to Rule 80C(b)(2), so that the requirement to re-open would be in a manner similar to Rules 15 and 123D.

Second, the Exchange proposes to delete subdivision (A) of Rule 80C(b)(2) in its entirety and mark the deleted text as "Reserved." As noted above, the requirements for reopening a security following a trading pause set forth in Rule 80C would be codified in proposed Rule 15(d)(6).

Rule 124

The Exchange proposes to amend subsection (c)(1) of Rule 124 (Midday Auction), describing the reopening process for the Midday Auction in the same manner as in Rule 123D for reopenings, by adding "pre-opening" before the word "indication" in four places and deleting the reference "to the Consolidated Tape" in the first sentence.

Rule 9217

The Exchange also proposes to amend Rule 9217, which sets forth the list of rules under which a member organization or covered person may be subject to a fine under a minor rule violation plan as set forth in Rule 9216(b). Rule 9217 permits a summary fine for violations of Rule 123D requirements for DMMs relating to openings, reopenings, delayed openings, trading halts, and tape indications. The Exchange proposes to delete the clause "tape indications" to reflect elimination of mandatory indications from Rule 123D. The Exchange believes this proposed change would add transparency and clarity to the Exchange's rules.

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Because of the technology changes associated with the proposed rule change, the Exchange will announce by Trader Update the implementation date of the changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[27] in general, and furthers the objectives of Section 6(b)(5) of the Act,[28] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest.

The Exchange believes that streamlining and consolidating pre-opening indications into a single rule (Rule 15) from two (Rules 15 and 123D) would remove impediments to and perfect the mechanism of a free and open market because it would set forth in a single rule the requirements for pre-opening indications, thereby promoting transparency by using consistent terminology for rules governing equities trading and ensuring that members, regulators, and the public can more easily navigate the Exchange's rulebook.

The Exchange believes that adopting new single-wide (5% change) and double-wide (10% change if S&P 500 futures move 2%) percentage parameters for the publication of pre-opening indications would remove impediments to and perfect the mechanism of a free and open market by requiring issuance of more pre-opening indications than currently during times of market stress, thereby increasing the amount of information available in the pre-market and improving the quality of price discovery at the opening. The proposed rule therefore promotes just and equitable principles of trade because it would expand the amount of pre-opening information available to the marketplace, thereby promoting transparency. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

The Exchange believes that amending Rule 123D to specify when a DMM may effect an opening electronically would remove impediments to and perfect the mechanism of a free and open market by promoting transparency in Exchange rules regarding under what circumstances a DMM may effect an opening electronically. The Exchange believes that the proposed parameters for when a DMM may open a security electronically, which would be 4% on regular trading days and doubled to 8% in times of market stress, would remove impediments to and perfect the mechanism of a free and open market by reducing the number of manual openings and enabling more securities to open closer to 9:30 a.m. ET on extremely volatile trading days, thereby providing customers and the investing public with greater certainty of a timely open in circumstances of extreme market stress. The Exchange further believes that the proposal would advance the efficiency and transparency of the opening process, thereby fostering accurate price discovery at the open of trading. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

The Exchange believes that deleting Rule 48 and moving the applicable provisions to Rules 15 and 123D would remove impediments to and perfect the mechanism of a free and open market by reducing reliance on Rule 48 during extremely volatile trading days. Rather, as proposed, the need for the CEO of the Exchange to temporarily suspend either pre-opening indications or the need for prior Floor Official approval before opening or reopening a security would be under more narrow circumstances of when a Floor-wide event would impair the Exchange's ability to conduct a fair and orderly open or reopening. As discussed above, the proposed amendments to Rule 15 and 123D to provide for parameters on days with extreme market-wide volatility would obviate the need for the current Rule 48 ability to lift the requirements for pre-opening indications or prior Floor Official approval during extreme market-wide volatility. The Exchange further believes that the proposal would advance the efficiency and transparency of the opening process, thereby fostering accurate price discovery at the open of trading. For the same reasons, the proposal is also designed to protect investors as well as the public interest.

The Exchange believes that making corresponding conforming changes to Rules 80C, 124 and 9217 would remove impediments to and perfects the mechanism of a free and open market by reducing potential confusion and adding transparency and clarity to the Exchange's rules, thereby ensuring that members, regulators and the public can more easily navigate and understand the Exchange's rulebook.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but rather promote greater efficiency and transparency at the open of trading on the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2016–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

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[27] 15 U.S.C. 78f(b).

[28] 15 U.S.C. 78f(b)(5).

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–24 and should be submitted on or before April 27, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07838 Filed 4–5–16; 8:45 am]

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[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77483; File No. SR–NSX–2016–01]

Self-Regulatory Organizations; National Stock Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt Exchange Rule 11.26 To Implement the Regulation NMS Plan To Implement a Tick Size Pilot Program

March 31, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 29, 2016, National Stock Exchange, Inc. ("NSX" or the "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change, as described in Items I and II below, which Items have been substantially prepared by the Exchange. The Exchange has designated this proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)(iii)[4] thereunder, which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to adopt Exchange Rule 11.26 to implement the Regulation NMS Plan to Implement a Tick Size Pilot Program (the "Plan"). Specifically, the Exchange has proposed Rule 11.26(b) to set forth the requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan. The proposed rule change is substantially similar to proposed rule changes recently approved or published by the Commission for the Bats BZX Exchange, Inc. f/k/a BATS Exchange, Inc. ("BZX") to adopt BZX Rule 11.27(b) which also sets forth requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan.[5] The Exchange has designated this proposal as "non-controversial" and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.[6]

The text of the proposed rule change is available at the Exchange's Web site at *www.nsx.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On August 25, 2014, NYSE Group, Inc., on behalf of BZX, Chicago Stock Exchange, Inc., Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc. ("FINRA"), NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the Nasdaq Stock Market LLC, New York Stock Exchange LLC ("NYSE"), NYSE MKT LLC, and NYSE Arca, Inc. (collectively "Participants"), filed with the Commission, pursuant to Section 11A of the Act[7] and Rule 608 of Regulation NMS thereunder,[8] the Plan to Implement a Tick Size Pilot Program ("Pilot").[9] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[10] The Plan[11] was published for comment in the **Federal Register** on November 7, 2014 and was thereafter approved by the Commission, as modified, on May 6, 2015.[12] On November 6, 2015, the Commission granted the Participants an exemption from implementing the Plan until October 3, 2016.[13] On March 3, 2016, the Commission noticed an amendment to the Plan adding NSX as a Participant.[14]

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stocks of small-capitalization companies. Each Participant is required to comply, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan. As is described more fully below, the proposed rules would require ETP Holders[15] to comply with the applicable data collection requirements of the Plan.[16]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6)(iii).

[5] See Securities Exchange Act Release Nos. 77105 (February 10, 2016), 81 FR 8112 (February 17, 2016) (order approving SR–BATS–2015–102); and 77310 (March 7, 2016) (notice for comment and immediate effectiveness of SR–BATS–2016–27).

[6] 17 CFR 240.19b–4(f)(6)(iii).

[7] 15 U.S.C. 78k–1.

[8] 17 CFR 242.608.

[9] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[10] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[11] Unless otherwise specified, capitalized terms used in this rule filing are based on the defined terms of the Plan.

[12] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27513 (May 13, 2015) (File No. 4–657) ("Approval Order").

[13] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (November 13, 2015) (File No. 4–657) (Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program).

[14] *See* Securities Exchange Act Release No. 77277 (March 3, 2016), 81 FR 12162 (March 8, 2016).

[15] An "ETP Holder" is a registrant of NSX to which NSX has issued an ETP. An "ETP" is defined as the term "ETP" is defined, in relevant part, as ". . . an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's trading facilities . . . ." *See* Exchange Rule 1.5.E(1).

[16] The Exchange proposes Interpretations and Policies .11 to Rule 11.26 to provide that the Rule

The Pilot will include stocks of companies with $3 billion or less in market capitalization, an average daily trading volume of one million shares or less, and a volume weighted average price of at least $2.00 for every trading day. The Pilot will consist of a control group of approximately 1,400 Pilot Securities and three test groups with 400 Pilot Securities in each (selected by a stratified random sampling process).[17] During the pilot, Pilot Securities in the control group will be quoted at the current tick size increment of $0.01 per share and will trade at the currently permitted increments. Pilot Securities in the first test group ("Test Group One") will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[18] Pilot Securities in the second test group ("Test Group Two") will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[19] Pilot Securities in the third test group ("Test Group Three") will be subject to the same quoting and trading increments as Test Group Two and also will be subject to the "Trade-at" requirement to prevent price matching by a market participant that is not displaying at a Trading Center's "Best Protected Bid" or "Best Protected Offer," unless an enumerated exception applies.[20] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS[21] will apply to the Trade-at requirement.

In approving the Plan, the Commission noted that the Trading Center data reporting requirements would facilitate an analysis of the effects of the Pilot on liquidity (*e.g.,* transaction costs by order size), execution quality (*e.g.,* speed of order executions), market maker activity, competition between trading venues (*e.g.,* routing frequency of market orders), transparency (*e.g.,* choice between displayed and hidden orders), and market dynamics (*e.g.,* rates and speed of order cancellations).[22] The Commission noted that Market Maker profitability data would assist the Commission in evaluating the effect, if any, of a widened tick increment on market marker profits and any corresponding changes in the liquidity of small-capitalization securities.[23]

Compliance With the Data Collection Requirements of the Plan

The Plan contains requirements for collecting and transmitting data to the Commission and to the public.[24] Specifically, Appendix B.I of the Plan (Market Quality Statistics) requires Trading Centers[25] to submit variety of market quality statistics, including information about an order's original size, whether the order was displayable or not, the cumulative number of orders, the cumulative number of shares of orders, and the cumulative number of shares executed within specific time increments, *e.g.,* from 30 seconds to less than 60 seconds after the time of order receipt. This information shall be categorized by security, order type, original order size, hidden status, and coverage under Rule 605.[26] Appendix B.I of the Plan also contains additional requirements for market orders and marketable limit orders, including the share-weighted average effective spread for executions of orders; the cumulative number of shares of orders executed with price improvement; and, for shares executed with price improvement, the share-weighted average amount per share that prices were improved.

Appendix B.II of the Plan (Market and Marketable Limit Order Data) requires Trading Centers to submit information relating to market orders and marketable limit orders, including the time of order receipt, order type, the order size, the National Best Bid and National Best Offer ("NBBO") quoted price, the NBBO quoted depth, the average execution price-share-weighted average, and the average execution time-share-weighted average.

The Plan requires Appendix B.I and B.II data to be submitted by Participants that operate a Trading Center, and by members of the Participants that operate Trading Centers. The Plan provides that each Participant that is the Designated Examining Authority ("DEA") for a member of the Participant that operates a Trading Center shall collect such data in a pipe delimited format, beginning six months prior to the Pilot Period and ending six months after the end of the Pilot Period. The Plan also requires the Participant, operating as DEA, to transmit this information to the SEC within 30 calendar days following month end.

The Exchange is therefore proposing Rule 11.26(b) to set forth the requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan. Proposed Rule 11.26(b) is substantially similar to proposed rule changes by BZX that were recently approved or published by the Commission to adopt BZX Rule 11.27(b) which also sets forth requirements for the collection and transmission of data pursuant to Appendices B and C of the Plan.[27]

Proposed Rule 11.26(b)(1) requires that an ETP Holder that operates a Trading Center shall establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the data collection and transmission requirements of Items I and II to Appendix B of the Plan, and an ETP Holder that is a Market Maker[28] shall establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the data collection and transmission requirements of Item IV of Appendix B of the Plan and Item I of Appendix C of the Plan.

Proposed Rule 11.26(b)(2) provides that the Exchange shall collect and transmit to the SEC the data described in Items I and II of Appendix B of the Plan relating to trading activity in Pre-Pilot Securities and Pilot Securities on a Trading Center operated by the Exchange. The Exchange shall transmit such data to the SEC in a pipe delimited format, on a disaggregated basis by Trading Center, within 30 calendar days following month end for: (i) Each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) each Pilot Security for the

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shall be in effect during a pilot period to coincide with the pilot period for the Plan (including any extensions to the pilot period for the Plan).

[17] *See* Section V of the Plan for identification of Pilot Securities, including criteria for selection and grouping.

[18] *See* Section VI(B) of the Plan.

[19] *See* Section VI(C) of the Plan.

[20] *See* Section VI(D) of the Plan.

[21] 17 CFR 242.611.

[22] *See* Approval Order, 80 FR at 27543.

[23] *Id.*

[24] The Exchange is also required by the Plan to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with applicable quoting and trading requirements specified in the Plan. The Exchange intends to separately propose rules that would require compliance by its ETP Holders with the applicable quoting and trading requirements specified in the Plan, and has reserved Paragraph (a) for such rules.

[25] The Plan incorporates the definition of a "Trading Center" from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a "Trading Center" as "a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent." *See* 17 CFR 242.600(b).

[26] 17 CFR 242.605.

[27] *See supra,* note 5.

[28] The Plan defines a Market Maker as "a dealer registered with any self-regulatory organization, in accordance with the rules thereof, as (i) a market maker or (ii) a liquidity provider with an obligation to maintain continuous, two-sided trading interest."

period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period. The Exchange also shall make such data publicly available on the Exchange Web site on a monthly basis at no charge and will not identify the ETP Holder that generated the data.

Appendix B.IV (Daily Market Maker Participation Statistics) requires a Participant to collect data related to Market Maker participation from each Market Maker engaging in trading activity on a Trading Center operated by the Participant. The Exchange is therefore proposing Rule 11.26(b)(3) to gather data about a Market Maker's participation in Pilot Securities and Pre-Pilot Data Collection Securities. Proposed Rule 11.26(b)(3)(A) provides that an ETP Holder that is a Market Maker shall collect and transmit to its DEA data relating to Item IV of Appendix B of the Plan with respect to activity conducted on any Trading Center in Pilot Securities and Pre-Pilot Data Collection Securities in furtherance of its status as a registered Market Maker, including a Trading Center that executes trades otherwise than on a national securities exchange, for transactions that have settled or reached settlement date. The proposed rule requires Market Makers to transmit such data in a format required by their DEA, by 12:00 p.m. EST on T + 4 for: (i) Transactions in each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) for transactions in each Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period.

The Exchange understands that some ETP Holders may have a DEA that is not a Participant to the Plan and that such non-Participant DEA would not be subject to the Plan's data collection requirements. In such case, a DEA that is not a Participant of the Plan would not be required to collect the required data and may not establish procedures for those ETP Holders for which it acts as DEA to report the data required under subparagraphs (b)(3)(A) of Rule 11.26 and in accordance with Item IV of Appendix B of the Plan. Therefore, the Exchange proposes to adopt subparagraph (b)(3)(B) to Rule 11.26 to require an ETP Holder that is a Market Maker whose DEA is not a Participant to the Plan to transmit the data collected pursuant to paragraph (3)(A) of Rule 11.26(b) to FINRA, which is a Participant to the Plan and will collect data relating to Item IV of Appendix B of the Plan on behalf of the Participants. For Market Makers for which it is the DEA, FINRA issued a Market Maker Transaction Data Technical Specification to collect data on Pre-Pilot Data Collection Securities and Pilot Securities from Trading Centers to comply with the Plan's data collection requirements.[29]

Proposed Rule 11.26(b)(3)(C) provides that the Exchange shall transmit the data collected by the DEA or FINRA pursuant to Rule 11.26(b)(3)(A) and (B) above relating to Market Maker activity on a Trading Center operated by the Exchange to the SEC in a pipe delimited format within 30 calendar days following month end. The Exchange shall also make such data publicly available on the Exchange Web site on a monthly basis at no charge and shall not identify the Trading Center that generated the data.

Appendix C.I (Market Maker Profitability) requires a Participant to collect data related to Market Maker profitability from each Market Maker for which it is the DEA. Specifically, the Participant is required to collect the total number of shares of orders executed by the Market Maker; the raw Market Maker realized trading profits, and the raw Market Maker unrealized trading profits. Data shall be collected for dates starting six months prior to the Pilot Period through six months after the end of the Pilot Period. This data shall be collected on a monthly basis, to be provided in a pipe delimited format to the Participant, as DEA, within 30 calendar days following month end. Appendix C.II (Aggregated Market Maker Profitability) requires the Participant, as DEA, to aggregate the Appendix C.I data, and to categorize this data by security as well as by the control group and each Test Group. That aggregated data shall contain information relating to total raw Market Maker realized trading profits, volume-weighted average of raw Market Maker realized trading profits, the total raw Market Maker unrealized trading profits, and the volume-weighted average of Market Maker unrealized trading profits.

The Exchange is therefore proposing Rule 11.26(b)(4) to set forth the requirements for the collection and transmission of data pursuant to Appendix C.I of the Plan. Proposed Rule 11.26(b)(4)(A) requires that an ETP Holder that is a Market Maker shall collect and transmit to its DEA the data described in Item I of Appendix C of the Plan with respect to executions in Pilot Securities that have settled or reached settlement date that were executed on any Trading Center. The proposed rule also requires ETP Holders to provide such data in a format required by its their DEA by 12 p.m. EST on T + 4 for executions during and outside of Regular Trading Hours in each: (i) Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period.

For the same reasons set forth above for subparagraph (b)(3)(B) to Rule 11.26, the Exchange proposes to adopt subparagraph (b)(4)(B) to Rule 11.26 to require an ETP Holder that is a Market Maker whose DEA is not a Participant to the Plan to transmit the data collected pursuant to paragraph (4)(A) of Rule 11.26(b) to FINRA. As stated above, FINRA is a Participant to the Plan and is to collect data relating to Item I of Appendix C of the Plan on behalf of the Participants. For Market Makers for which it is the DEA, FINRA issued a Market Maker Transaction Data Technical Specification to collect data on Pre-Pilot Data Collection Securities and Pilot Securities from Trading Centers to comply with the Plan's data collection requirements.[30]

The Exchange is also adopting a rule describing the manner in which Market Maker participation will be calculated. Item III of Appendix B of the Plan requires each Participant that is a national securities exchange to collect daily Market Maker registration statistics categorized by security, including the following information: (i) Ticker symbol; (ii) the Participant exchange; (iii) number of registered market makers; and (iv) the number of other registered liquidity providers. Therefore, the Exchange proposes to adopt Rule 11.26(b)(5) providing that the Exchange shall collect and transmit to the SEC the data described in Item III of Appendix B of the Plan relating to daily Market Maker registration statistics in a pipe delimited format within 30 calendar days following month end for: (i) Transactions in each Pre-Pilot Data Collection Security for the period beginning six months prior to the Pilot Period through the trading day immediately preceding the Pilot Period; and (ii) transactions in each Pilot Security for the period beginning on the first day of the Pilot Period through six months after the end of the Pilot Period. The Exchange notes that, as of the date of this filing, it does not have any registered Market Makers and therefore will not have daily Market Maker registration statistics to collect or transmit to the SEC or to FINRA pursuant to Item III of Appendix B the Plan as of the effective date of the data collection requirements, April 4, 2016.

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[29] FINRA members for which FINRA is their DEA should refer to the Market Maker Transaction Data Technical Specification on the FINRA Web site at *http://www.finra.org/sites/default/files/market-maker-transaction-data-tech-specs.pdf.*

[30] *Id.*

The Exchange is also proposing, through Interpretations and Policies, to clarify other aspects of the data collection requirements.[31] Proposed Interpretations and Policies .02 relates to the use of the retail investor order flag for purposes of Appendix B.II(n) reporting. The Plan currently states that market and marketable limit orders shall include a "yes/no" field relating to the Retail Investor Order flag. The Exchange is proposing Interpretations and Policies .02 to clarify that, for purposes of the reporting requirement in Appendix B.II(n), a Trading Center shall report "y" to their DEA where it is relying upon the Retail Investor Order exception to Test Groups Two and Three, and "n" for all other instances.[32] The Exchange believes that requiring the identification of a Retail Investor Orders only where the exception may apply (*i.e.,* Pilot Securities in Test Groups Two and Three) is consistent with Appendix B.II(n).

Interpretations and Policies .03 requires that ETP Holders populate a field to identify to their DEA whether an order is affected by the bands in place pursuant to the National Market System Plan to Address Extraordinary Market Volatility.[33] Pursuant to the Limit-Up Limit-Down Plan, between 9:30 a.m. and 4:00 p.m., the Securities Information Processor ("SIP") calculates a lower price band and an upper price band for each NMS stock. These price bands represent a specified percentage above or below the stock's reference price, which generally is calculated based on reported transactions in that stock over the preceding five minutes. When one side of the market for an individual security is outside the applicable price band, the SIP identifies that quotation as non-executable. When the other side of the market reaches the applicable price band (*e.g.,* the offer reaches the lower price band), the security enters a Limit State. The stock would exit a Limit State if, within 15 seconds of entering the Limit State, all Limit State Quotations were executed or canceled in their entirety. If the security does not exit a Limit State within 15 seconds, then the primary listing exchange declares a five-minute trading pause, which would be applicable to all markets trading the security.

The Exchange and the other Participants have determined that it is appropriate to create a new flag for reporting orders that are affected by the Limit-Up Limit-Down bands. Accordingly, a Trading Center shall report a value of "Y" to their DEA when the ability of an order to execute has been affected by the Limit-Up Limit-Down bands in effect at the time of order receipt. A Trading Center shall report a value of "N" to their DEA when the ability of an order to execute has not been affected by the Limit-Up Limit-Down bands in effect at the time of order receipt.

Interpretations and Policies .03 also requires, for securities that may trade in a foreign market, that the Participant indicate whether the order was handled domestically, or routed to a foreign venue. Accordingly, the Participant will indicate, for purposes of Appendix B.I, whether the order was: (1) Fully executed domestically, or (2) fully or partially executed on a foreign market. For purposes of Appendix B.II, the Participant will classify all orders in securities that may trade in a foreign market Pilot and Pre-Pilot Securities as: (1) Directed to a domestic venue for execution; (2) may only be directed to a foreign venue for execution; or (3) was fully or partially directed to a foreign venue at the discretion of the member. The Exchange believes that this proposed flag will better identify orders in securities that may trade in a foreign market, as such orders that were routed to foreign venues would not be subject to the Plan's quoting and trading requirements, and could otherwise compromise the integrity of the data.

Interpretations and Policies .04 relates to the time ranges specified in Appendix B.I.a(14), B.I.a(15), B.I.a(21) and B.I.a(22).[34] The Exchange and the other Participants have determined that it is appropriate to change the reporting times in these provisions to require more granular reporting for these categories. Accordingly, the Exchange proposes to add Appendix B.I.a(14A), which will require Trading Centers to report the cumulative number of shares of orders executed from 100 microseconds to less than 1 millisecond after the time of order receipt. Appendix B.I.a(15) will be changed to require the cumulative number of shares of orders executed from 1 millisecond to less than 100 milliseconds after the time of order receipt. The Exchange also proposes to add Appendix B.I.a(21A), which will require Trading Centers to report the cumulative number of shares of orders canceled from 100 microseconds to less than 1 millisecond after the time of order receipt. Appendix B.I.a(22) will be changed to require the cumulative number of shares of orders canceled from 1 millisecond to less than 100 milliseconds after the time of order receipt. The Exchange believes that these new reporting requirements will contribute to a meaningful analysis of the Pilot by producing more granular data on these points.[35]

Interpretations and Policies .05 relates to the relevant measurement for purposes of Appendix B.I.a(31)–(33) reporting. Currently, the Plan states that this data shall be reported as of the time of order execution. The Exchange and the other Participants believe that this information should more properly be captured at the time of order receipt as evaluating share-weighted average prices at the time of order receipt is more consistent with the goal of observing the effect of the Pilot on the liquidity of Pilot Securities. The Exchange is therefore proposing to make this change through Interpretations and

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[31] The Exchange is also proposing Interpretations and Policies .01 to Rule 11.26 to clarify that certain enumerated terms used throughout Rule 11.26 shall have the same meaning as set forth in the Plan.

[32] FINRA, on behalf of the Plan Participants at the time submitted a letter to Commission requesting exemption from certain provisions of the Plan related to data collection. *See* letter from Marcia E. Asquith, Senior Vice President and Corporate Secretary, FINRA dated December 9, 2015 to Robert W. Errett, Deputy Secretary, Commission ("Exemption Request"). The Commission, pursuant to its authority under Rule 608(e) of Regulation NMS, granted BZX, as of February 10, 2016, a limited exemption from the requirement to comply with certain provisions of the Plan as specified in the letter and noted herein. *See e.g.,* letter from David Shillman, Associate Director, Division of Trading and Markets, Commission to Eric Swanson, General Counsel, BZX, dated February 10, 2016 ("Exemption Letter"). NSX was not a Plan Participant at the time that such exemptions were requested or granted and respectfully requests that the Commission grant to it the same exemptions that the Commission granted to the other Plan Participants.

[33] *See* National Market System Plan to Address Extraordinary Market Volatility, Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (File No. 4–631) ("Limit-Up Limit-Down Plan").

[34] Specifically, Appendix B.I.a(14) requires reporting of the cumulative number of shares of orders executed from 0 to less than 100 microseconds after the time of order receipt; Appendix B.I.a(15) requires reporting of the cumulative number of shares of orders executed from 100 microseconds to less than 100 milliseconds after the time of order receipt; Appendix B.I.a(21) requires reporting of the cumulative number of shares of orders cancelled from 0 to less than 100 microseconds after the time of order receipt; and Appendix B.I.a(22) requires reporting of the cumulative number of shares of orders cancelled from 100 microseconds to less than 100 milliseconds after the time of order receipt.

[35] On February 10, 2016, the Commission granted BZX an exemption from Rule 608(c) related to this provision. *See* Exemption Letter, *supra,* note 32. NSX requests that the Commission grant to it this same exemption.

Policies .05.[36] This change will make these provisions consistent with the remainder of the statistics in Appendix B.I.a, which are all based on order receipt.

Interpretations and Policies .06 addresses the status of not-held and auction orders for purposes of Appendix B.I reporting. Currently, Appendix B.I sets forth eight categories of orders, including market orders, marketable limit orders, and inside-the-quote resting limit orders, for which daily market quality statistics must be reported. Currently, Appendix B.I does not provide a category for not held orders, clean cross orders, auction orders, or orders received when the NBBO is crossed. The Exchange and the other Participants have determined that it is appropriate to include separate categories for these orders types for purposes of Appendix B reporting. The Exchange is therefore proposing Interpretations and Policies .06 to provide that not held orders shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (18). Clean cross orders shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (19); auction orders shall be included an as order type for purposes of Appendix B reporting, and shall be assigned the number (20);[37] and orders that cannot otherwise be classified, including, for example, orders received when the NBBO is crossed shall be included as an order type for purposes of Appendix B reporting, and shall be assigned the number (21). All of these orders already are included in the scope of Appendix B; however, without this proposed change, these order types would be categorized with other orders, such as regular held orders, that should be able to be fully executed upon receipt, which would compromise the value of this data.

The Exchange is proposing Interpretations and Policies .07 to clarify the scope of the Plan as it relates to ETP Holders that only execute orders limited purposes. Specifically, the Exchange and the other Participants believe that an ETP Holder that only executes orders otherwise than on a national securities exchange for the purpose of: (1) Correcting a bona fide error related to the execution of a customer order; (2) purchasing a security from a customer at a nominal price solely for purposes of liquidating the customer's position; or (3) completing the fractional share portion of an order[38] shall not be deemed a Trading Center for purposes of Appendix B to the Plan. The Exchange is therefore proposing Interpretations and Policies .09 [sic] to make this clarification.

The Exchange is proposing Interpretations and Policies .08 to clarify that, for purposes of the Plan, Trading Centers must begin the data collection required pursuant to Appendix B.I.a(1) through B.II.(y) of the Plan and Item I of Appendix C of the Plan on April 4, 2016. While the Exchange or the ETP Holder's DEA will provide the information required by Appendix B and C of the Plan during the Pilot Period, the requirement that the Exchange or their DEA provide information to the SEC within 30 days following month end and make such data publicly available on its Web site pursuant to Appendix B and C shall commence six months prior to the beginning of the Pilot Period.[39]

The Exchange is proposing Interpretations and Policies .09 to address the requirement in Appendix C.I(b) of the Plan that the calculation of raw Market Maker realized trading profits utilize a last in, first out ("LIFO")-like method to determine which share prices shall be used in that calculation. The Exchange and the other Participants believe that it is more appropriate to utilize a methodology that yields LIFO-like results, rather than utilizing a LIFO-like method, and the Exchange is therefore proposing Interpretations and Policies .09 to make this change.[40] The Exchange is proposing that, for purposes of Item I of Appendix C, the Participants shall calculate daily Market Maker realized profitability statistics for each trading day on a daily LIFO basis using reported trade price and shall include only trades executed on the subject trading day. The daily LIFO calculation shall not include any positions carried over from previous trading days. For purposes of Item I.c of Appendix C, the Participants shall calculate daily Market Maker unrealized profitability statistics for each trading day on an average price basis. Specifically, the Participants must calculate the volume weighted average price of the excess (deficit) of buy volume over sell volume for the current trading day using reported trade price. The gain (loss) of the excess (deficit) of buy volume over sell volume shall be determined by using the volume weighted average price compared to the closing price of the security as reported by the primary listing exchange. In reporting unrealized trading profits, the Participant shall also report the number of excess (deficit) shares held by the Market Maker, the volume weighted average price of that excess (deficit) and the closing price of the security as reported by the primary listing exchange used in reporting unrealized profit.[41]

Finally, the Exchange is proposing Interpretations and Policies .10 to address the securities that will be used for data collection purposes prior to the commencement of the Pilot. The Exchange and the other Participants have determined that it is appropriate to collect data for a group of securities that is larger, and using different quantitative thresholds, than the group of securities that will be Pilot Securities. The Exchange is therefore proposing Interpretations and Policies .10 to define "Pre-Pilot Data Collection Securities" as the securities designated by the Participants for purposes of the data collection requirements described in Items I, II and IV of Appendix B and Item I of Appendix C of the Plan for the period beginning six months prior to the Pilot Period and ending on the trading day immediately preceding the Pilot Period. The Participants shall compile the list of Pre-Pilot Data Collection Securities by selecting all NMS stocks with a market capitalization of $5 billion or less, a Consolidated Average Daily Volume (CADV) of 2 million shares or less and a closing price of $1 per share or more. The market capitalization and the closing price thresholds shall be applied to the last day of the Pre-Pilot measurement period, and the CADV threshold shall be applied to the duration of the Pre-Pilot measurement period. The Pre-Pilot measurement period shall be the three calendar months ending on the day when the Pre-Pilot Data Collection Securities are selected. The Pre-Pilot Data Collection Securities shall be selected thirty days prior to the commencement of the six-month Pre-Pilot Period. On the trading day that is the first trading day of the Pilot Period through six months after the end of the Pilot Period, the data collection requirements will become applicable to the Pilot Securities only. A Pilot Security will only be eligible to be included in a Test Group if it was a Pre-Pilot Security.

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[36] On February 10, 2016, the Commission granted BZX an exemption from Rule 608(c) related to this provision. *See* Exemption Letter, *supra,* note 32. NSX requests that the Commission grant to it this same exemption.

[37] The Exchange notes that, as of the date of this rule filing, it does not offer order types specifically defined as "not held," "clean cross," or "auction order."

[38] The Exchange notes that where an ETP Holder purchases a fractional share from a customer, the Trading Center that executes the remaining whole shares of that customer order would subject to subject to Appendix B of the Plan.

[39] In the Approval Order, the SEC noted that the Pilot shall be implemented within one year of the date of publication, *i.e.,* by May 6, 2016. *See* Approval Order, 80 FR at 27545. The SEC subsequently extended the implementation date approximately five months to October 3, 2016. *See supra,* note 13. *See also* Letter dated November 4, 2015 from Brendon J. Weiss, Co-Head, Government Affairs, Intercontinental Exchange/NYSE, to Brent J. Fields, Secretary, Commission (requesting the data collection period be extended until six months after the requisite SRO rules are approved, and the implementation data of the Tick Size Pilot until six months thereafter).

[40] Appendix C.I currently requires Market Maker profitability statistics to include (1) the total number of shares of orders executed by the Market Maker; (2) raw Market Maker realized trading profits, which is the difference between the market value of Market Maker shares and the market value of Market Maker purchases, using a LIFO-like method; and (3) raw Market Maker unrealized trading profits, which is the difference between the purchase or sale price of the end-of-day inventory position of the Market Maker and the Closing Price. In the case of a short position, the Closing Price from the sale will be subtracted; in the case of a long position, the purchase price will be subtracted from the Closing Price.

[41] The Commission granted BZX, as of February 10, 2016, an exemption from Rule 608(c) related to this provision. *See* Exemption Letter, *supra,* note 30 [sic]. NSX requests that the Commission grant to it this same exemption.

Implementation Date

The proposed rule change will be effective on April 4, 2016.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[42] in general, and furthers the objectives of Section 6(b)(5) of the Act[43] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that this proposal is consistent with the Act because it implements and clarifies the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant of the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. The Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act because the proposal implements and clarifies the requirements of the Plan and applies specific obligations to ETP Holders in furtherance of compliance with the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that the data collection requirements for ETP Holders that operate Trading Centers will apply equally to all such ETP Holders, as will the data collection requirements for Market Makers.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[44] and Rule 19b–4(f)(6) thereunder.[45]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[46] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[47] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it would allow the Exchange to implement the proposed amendments on April 4, 2016, the date upon which the data collection requirements of the Plan become effective.[48] Therefore, the Commission hereby waives the operative delay and designates the proposal operative on April 4, 2016.[49]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NSX–2016–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSX–2016–01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSX–2016–01, and should be submitted on or before April 27, 2016.

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[42] 15 U.S.C. 78f(b).

[43] 15 U.S.C. 78f(b)(5).

[44] 15 U.S.C. 78s(b)(3)(A).

[45] 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

[46] 17 CFR 240.19b–4(f)(6).

[47] 17 CFR 240.19b–4(f)(6)(iii).

[48] *See* Securities Exchange Act Release No. 76382 (November 6, 2015), 80 FR 70284 (File No. 4–657) (Order Granting Exemption From Compliance With the National Market System Plan To Implement a Tick Size Pilot Program).

[49] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–07830 Filed 4–5–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Go EZ Corp.; Order of Suspension of Trading

April 4, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Go EZ Corp. ("GEZC") (CIK No. 314197) because of questions regarding the accuracy and adequacy of publicly disseminated information in press releases and public filings concerning, among other things, GEZC's business prospects, operations, and control. GEZC is a Delaware corporation whose principal place of business is listed as 6782 Collins Ave., Miami Beach, Florida. GEZC's common stock is quoted on OTC Link operated by OTC Markets Group, Inc. under the ticker symbol GEZC.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT, on April 4, 2016 through 11:59 p.m. EDT, on April 15, 2016.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2016–07967 Filed 4–4–16; 11:15 am]

BILLING CODE 8011–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Public Hearing

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold a public hearing on May 4, 2016, in Grantville, Pennsylvania. At this public hearing, the Commission will hear testimony on the projects listed in the **SUPPLEMENTARY INFORMATION** section of this notice. The Commission will also hear testimony on a proposed guidance for expiring project approvals and a proposed guidance for terminating review of a project application as well as proposals to amend its Regulatory Program Fee Schedule and the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin.* Such projects and proposals are intended to be scheduled for Commission action at its next business meeting, tentatively scheduled for June 16, 2016, which will be noticed separately. The public should take note that this public hearing will be the only opportunity to offer oral comment to the Commission for the listed projects and proposals. The deadline for the submission of written comments is May 16, 2016.

DATES: The public hearing will convene on May 4, 2016, at 7:00 p.m. The public hearing will end at 9:00 p.m. or at the conclusion of public testimony, whichever is sooner. The deadline for the submission of written comments is May 16, 2016.

ADDRESSES: The public hearing will be conducted at the East Hanover Township Municipal Building, Main Hall, 8848 Jonestown Road, Grantville, PA 17028 (parking lot entry off of Manada Gap Road; see *http://easthanovertwpdcpa.org/index.php/about-contact*).

FOR FURTHER INFORMATION CONTACT: Jason Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436.

Information concerning the applications for these projects is available at the SRBC Water Resource Portal at *www.srbc.net/wrp.* Additional supporting documents are available to inspect and copy in accordance with the Commission's Access to Records Policy at *www.srbc.net/pubinfo/docs/2009-02_Access_to_Records_Policy_20140115.pdf.*

SUPPLEMENTARY INFORMATION: The public hearing will cover a proposed guidance for expiring project approvals and a proposed guidance for terminating review of a project application as well as proposed amendments to its Regulatory Program Fee Schedule and the *Comprehensive Plan for the Water Resources of the Susquehanna River Basin,* as posted on the SRBC Public Participation Center Web page at *www.srbc.net/pubinfo/publicparticipation.htm.* The public hearing will also cover the following projects:

Projects Scheduled for Action

1. Project Sponsor and Facility: Black Bear Waters, LLC (Lycoming Creek), Lewis Township, Lycoming County, Pa. Application for renewal of surface water withdrawal of up to 0.900 mgd (peak day) (Docket No. 20120303).
2. Project Sponsor and Facility: Blossburg Municipal Authority, Bloss Township, Tioga County, Pa. Application for renewal of groundwater withdrawal of up to 0.288 mgd (30-day average) from Route 15 Well (Docket No. 20120304).
3. Project Sponsor and Facility: Cabot Oil & Gas Corporation (Martins Creek), Harford Township, Susquehanna County, Pa. Application for surface water withdrawal of up to 0.500 mgd (peak day).
4. Project Sponsor and Facility: Todd and Gemma Campbell (Susquehanna River), Athens Township, Bradford County, Pa. Application for renewal of surface water withdrawal of up to 0.999 mgd (peak day) (Docket No. 20120609).
5. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.201 mgd (30-day average) from Well 1.
6. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.106 mgd (30-day average) from Well 3.

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[50] 17 CFR 200.30–3(a)(12).

7. Project Sponsor and Facility: Elizabethtown Area Water Authority, Elizabethtown Borough, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.130 mgd (30-day average) from Well 4.

8. Project Sponsor and Facility: Elizabethtown Area Water Authority, Mount Joy Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.187 mgd (30-day average) from Well 8.

9. Project Sponsor and Facility: Elizabethtown Area Water Authority, Mount Joy Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.216 mgd (30-day average) from Well 9.

10. Project Sponsor and Facility: EQT Production Company (Pine Creek), Porter Township, Lycoming County, Pa. Application for surface water withdrawal of up to 1.000 mgd (peak day).

11. Project Sponsor: Exelon Generation Company, LLC. Project Facility: Muddy Run Pumped Storage Project, Drumore and Martic Townships, Lancaster County, Pa. Application for an existing hydroelectric facility.

12. Project Sponsor and Facility: Manbel Devco I, LP, Manheim Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 4.320 mgd (30-day average) from the Belmont Quarry.

13. Project Sponsor and Facility: Mount Joy Borough Authority, East Donegal Township, Lancaster County, Pa. Modification to increase withdrawal limit from Well 1 by an additional 0.073 mgd (30-day average), for a total Well 1 withdrawal limit of 1.300 mgd (30-day average) (Docket No. 20110617).

14. Project Sponsor: New Enterprise Stone & Lime Co., Inc. Project Facility: Burkholder Quarry, Earl Township, Lancaster County, Pa. Application for groundwater withdrawal of up to 0.005 mgd (30-day average) from Sump 4.

15. Project Sponsor: New Enterprise Stone & Lime Co., Inc. Project Facility: Burkholder Quarry, Earl Township, Lancaster County, Pa. Modification to increase consumptive water use by an additional 0.099 mgd (peak day), for a total consumptive water use of up to 0.249 mgd (peak day) and to add an additional new source (Sump 4) (Docket No. 20040307).

16. Project Sponsor and Facility: Renovo Energy Center LLC (West Branch Susquehanna River), Renovo Borough, Clinton County, Pa. Application for surface water withdrawal of up to 0.612 mgd (peak day).

17. Project Sponsor and Facility: Renovo Energy Center LLC, Renovo Borough, Clinton County, Pa. Application for consumptive water use of up to 0.217 mgd (peak day).

18. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Newberry Operation, Newberry Township, York County, Pa. Application for groundwater withdrawal of up to 0.108 mgd (30-day average) from the Coppersmith Well.

19. Project Sponsor: SUEZ Water Pennsylvania Inc. Project Facility: Newberry Operation, Newberry Township, York County, Pa. Application for groundwater withdrawal of up to 0.200 mgd (30-day average) from Conley 1 Well.

20. Project Sponsor and Facility: Sugar Hollow Trout Park and Hatchery, Eaton Township, Wyoming County, Pa. Application for renewal of groundwater withdrawal of up to 0.864 mgd (30-day average) from Wells 1, 2, and 3 (the Hatchery Wellfield) (Docket No. 20100913).

21. Project Sponsor and Facility: Tioga Downs Racetrack, LLC, Town of Nichols, Tioga County, N.Y. Application for groundwater withdrawal of up to 0.099 mgd (30-day average) from the Racetrack Well.

22. Project Sponsor and Facility: Tioga Downs Racetrack, LLC, Town of Nichols, Tioga County, N.Y. Application for consumptive water use of up to 0.099 mgd (peak day).

Opportunity To Appear and Comment

Interested parties may appear at the hearing to offer comments to the Commission on any project or proposal listed above. The presiding officer reserves the right to limit oral statements in the interest of time and to otherwise control the course of the hearing. Rules of conduct will be posted on the Commission's Web site, *www.srbc.net,* prior to the hearing for review. The presiding officer reserves the right to modify or supplement such rules at the hearing. Written comments on any project listed above may also be mailed to Mr. Jason Oyler, General Counsel, Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pa. 17110–1788, or submitted electronically through *www.srbc.net/pubinfo/publicparticipation.htm.* Comments mailed or electronically submitted must be received by the Commission on or before May 16, 2016, to be considered.

Authority: Public Law 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: March 31, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–07799 Filed 4–5–16; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Thirty-First Meeting: RTCA Special Committee (213) Enhanced Flight Visions Systems/Synthetic Vision Systems (EFVS/SVS)(Joint With EUROCAE WG–79)

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Thirty-First RTCA Special Committee 213 Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Thirty-First RTCA Special Committee 213 meeting.

DATES: The meeting will be held May 10–12, 2016 from 8:30 a.m.–5:00 p.m.

ADDRESS: The meeting will be held at Thales, 3 Rue Toussaint Catros, 33185 Le Haillan, Bordeaux, France, Tel: (202) 330–0662.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680. Additional Points of Contract: Bruno Aymeric, *bruno.aymeric@fr.thalesgroup.com,* phone +33 5 56 13 66 79, mobile +33 6 31 84 51 96; Tim Etherington, *tjetheri@rockwellcollins.com,* phone (757) 864–5796, mobile (757) 690–3178; Patrick Krohn, *pkrohn@uasc.com,* phone (425) 602–1375, mobile (425) 829–1996. The RTCA SC–213 Web site has contact information to support the meetings.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 213. The agenda will include the following:

Tuesday, May 10, 2016

1. Plenary discussion (sign-in at 08:00 a.m.)
   a. Introductions and administrative items
   b. Review and approve minutes from last full plenary meeting
   c. Review of terms of reference and update work product dates

d. WG1, WG2, WG3 and WG4 status updates
e. Industry updates
f. Working group discussion

Wednesday, May 11, 2016

1. Plenary Discussion
   a. Working Group Discussion

Thursday, May 12, 2016

1. Plenary discussion
   a. Working group discussion
   b. Administrative items (new meeting location/dates, action items etc.)

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons who wish to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on April 1, 2016.

Latasha Robinson,

Management & Program Analyst, NextGen, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2016–07915 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice for LA/Ontario International Airport, Ontario, California

AGENCY: Federal Aviation Administration, (FAA), DOT.

ACTION: Notice

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by Los Angeles World Airports, for LA/Ontario International Airport under the provisions of 49 U.S.C. 47501 *et seq.* (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements.

DATES: The effective date of the FAA's determination on the noise exposure maps is April 6, 2016 and applicable March 29, 2016.

FOR FURTHER INFORMATION CONTACT: Victor Globa, Environmental Protection Specialist, Federal Aviation Administration, Los Angeles Airports District Office, Mailing Address: P.O. Box 92007, Los Angeles, California 90009–2007. Street Address: 15000 Aviation Boulevard, Hawthorne, California 90261. Telephone: 310/725–3637.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for LA/Ontario International Airport are in compliance with applicable requirements of Title 14, Code of Federal Regulations (CFR) Part 150 (hereinafter referred to as "Part 150"), effective March 29, 2016. Under 49 U.S.C. Section 47503 of the Aviation Safety and Noise Abatement Act (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the noise exposure maps and accompanying documentation submitted by Los Angeles World Airports. The documentation that constitutes the "Noise Exposure Maps" as defined in Section 150.7 of part 150 includes: Figure 13, Existing Conditions (2015) Noise Exposure Map; and Figure 14, Forecast Conditions (2020) Noise Exposure Map. The Noise Exposure Maps contain current and forecast information including the depiction of: The airport and its boundary; the runway configurations; land uses such as residential, commercial, industrial, and open space/recreational land use; locations of noise sensitive public buildings (such as schools, hospitals, and historic properties on or eligible for the National Register of Historic Places); and the Community Noise Equivalent Level (CNEL) 65, 70, and 75 decibel airport noise contours resulting from existing and forecast airport operations. The frequency of airport operations is described in Section 2.1.2 of the Noise Exposure Map Update report. Flight tracks associated with LA/Ontario International Airport are depicted in Figures 8 through 11. The LA/Ontario International Airport noise monitoring system is described in Appendix B, Program Element 6.5, and monitoring locations are shown on Exhibits 8, 9, 12, 13, 14 and 15 of the Noise Exposure Map Update report. Estimates of the number of people residing within the CNEL contours is located in Section 3.2.2 of the Noise Exposure Map Update report. The FAA has determined that these noise exposure maps and accompanying documentation are in compliance with applicable requirements. This determination is applicable on March 29, 2016.

FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21 of Part 150, that the statutorily required consultation has been accomplished.

Copies of the full noise exposure map documentation and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, Western-Pacific Region Office, Airports Division, Room 3012, 15000 Aviation Boulevard, Hawthorne, California 90261
Federal Aviation Administration, Los Angeles Airports District Office, Room 3000, 15000 Aviation Boulevard, Hawthorne, California 90261
LA/Ontario International Airport, Administration Office, 1923 E. Avion Street, Ontario, California 91761
Los Angeles World Airports, Attention: Mr. Scott Tatro, Airport Environmental Manager II, 7301 World Way West, Los Angeles, California 90045

Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Hawthorne, California, March 29, 2016.

M. Melissa King,

Acting Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 2016–07914 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty-Sixth Meeting: RTCA Special Committee (216) Aeronautical Systems Security

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of Twenty-Sixth RTCA Special Committee 216 Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Twenty-Sixth RTCA Special Committee 216 meeting.

DATES: The meeting will be held May 3–5, 2016 from 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036, Tel: (202) 330–0662.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 216. The agenda will include the following:

Tuesday, May 3, 2016 (9:00 a.m.–5:00 p.m.)

1. Welcome and Administrative Remarks
2. Introductions
3. Agenda Review
4. Meeting-Minutes Review
5. Reminder RTCA Overview Presentation
6. SC–216 New Scope and Terms of Reference review
7. Overview of WG–72
8. Overview of DO–356, Airworthiness Security Methods and Considerations
9. SC–216 Structure and Organization of Work
10. Proposed Schedule
11. Date, Place and Time of Next Meeting
12. New Business
13. Adjourn Plenary

Wednesday, May 4, 2016 (9:00 a.m.–5:00 p.m.)

1. Continuation of Plenary or Working Group Sessions

Thursday, May 5, 2016 (9:00 a.m.–12:00 p.m.)

1. Continuation of Plenary or Working Group Sessions

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons who wish to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on April 1, 2016.

Latasha Robinson,

Management & Program Analyst, NextGen, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2016–07916 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2016–0019]

Notice of Proposed Policy Statement on the Implementation of the Phased Increase in Domestic Content Under the Buy America Waiver for Rolling Stock

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of proposed policy statement and request for comments.

SUMMARY: This notice proposes a statement of policy regarding the implementation of the phased increase in domestic content for rolling stock under the Federal Transit Administration's (FTA) Buy America statute, as amended by the Fixing America's Surface Transportation (FAST) Act. The FAST Act was signed into law on December 4, 2015, with an effective date of October 1, 2015. FTA seeks comments from all interested parties. After consideration of the comments, FTA will issue a second **Federal Register** notice responding to comments and noting any changes made to the policy statement as a result of the comments received.

DATES: Comments must be received by May 6, 2016. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Please submit your comments by one of the following means, identifying your submissions by docket number FTA–2016–0019:

1. *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site.
2. *Fax:* (202) 493–2251.
3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must make reference to the "Federal Transit Administration" and include docket number FTA–2016–0019. Due to the security procedures in effect since October 2011, mail received through the U.S. Postal Service may be subject to delays. Parties making submissions responsive to this notice should consider using an express mail firm to ensure the prompt filing of any submissions not filed electronically or by hand. Note that all submissions received, including any personal information therein, will be posted without change or alteration to *http://www.regulations.gov.* For more information, you may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000 (65 FR 19477), or you may visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Cecelia Comito, Assistant Chief Counsel, Office of the Chief Counsel, phone: (202) 366–2217 or email, *Cecelia.Comito@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The purpose of this notice is to propose a statement of policy that will clarify how to apply FTA's Buy America requirements to procurements for rolling stock with delivery dates or options in FY2018 through FY2020 and beyond. The FAST Act amended the rolling stock waiver in 49 U.S.C. 5323(j)(2)(C) to provide for a phased increase in the domestic content of rolling stock for FY2018–FY2019 and FY2020 and beyond:

> (j) Buy America.
>
> (1) In general. The Secretary may obligate an amount that may be appropriated to carry out this chapter for a project only if the steel, iron, and manufactured goods used in the project are produced in the United States.
>
> (2) Waiver. The Secretary may waive paragraph (1) of this subsection if the Secretary finds that:
>
> * * * * *
>
> (C) when procuring rolling stock (including train control, communication, traction power equipment, and rolling stock prototypes) under this chapter
>
> (i) the cost of components and subcomponents produced in the United States
>
> (I) for fiscal years 2016 and 2017, is more than 60 percent of the cost of all components of the rolling stock;
>
> (II) for fiscal years 2018 and 2019, is more than 65 percent of the cost of all components of the rolling stock; and
>
> (III) for fiscal years 2020 and each fiscal year thereafter, is more than 70 percent of the cost of all components of the rolling stock; and
>
> (ii) final assembly of the rolling stock has occurred in the United States . . .

Recipients may enter into rolling stock contracts under 49 U.S.C. 5325(e) for up to five years for buses and seven years for railcars. In FTA Circular 4220.1F, "Third Party Contracting Guidance," FTA interpreted these five- and seven-year periods as covering the recipient's "material requirements" for rolling stock and replacement needs from the first day when the contract becomes effective to its "material requirements" at the end of the fifth or seventh year, as applicable. FTA has not required that "the recipient must obtain delivery, acceptance, or even fabrication in five or seven years. Instead it means only that FTA limits a contract to purchasing no more than the recipient's material requirements for rolling stock or replacement parts for five or seven years based on the effective date of the contract." *See* FTA Circular 4220.1F, Chapter IV, page 23. Therefore, options for vehicles can be exercised within the five- or seven-year contract term, even if the vehicles will be delivered after the contract term.

Recipients have asked FTA to provide specific guidance on the applicability of the FAST Act's new Buy America provisions to contracts entered into before or after October 1, 2015, the effective date of the FAST Act.

II. Proposed Policy

FTA's Buy America requirements focus on two points in time: (1) "When *procuring* rolling stock," which FTA interprets as the date of contracting; and (2) "the cost of components and subcomponents *produced* in the United States for fiscal years . . .", which FTA interprets as the date of delivery of the vehicle.

Individual and Joint Procurements. FTA interprets the statute to require that if a recipient or group of recipients enter into a contract for rolling stock after the effective date of the FAST Act, *i.e.,* October 1, 2015, then the new FAST Act provisions for the date of delivery of the rolling stock apply. Thus, for vehicles delivered in FY2018 and FY2019, the domestic content must be more than 65 percent, and for vehicles delivered in FY2020 and beyond, the domestic content must be more than 70 percent. These delivery provisions apply to contracts signed after the effective date of the FAST Act, *i.e.,* October 1, 2015, unless a waiver is granted.

The FAST Act amendments do not apply to contracts entered into before the effective date of the FAST Act, *i.e.,* October 1, 2015, even if the contract provides for the delivery of vehicles after FY2017. For contracts entered into before October 1, 2015, FTA proposes to continue to permit options to be exercised during the contract period even if the vehicles will be delivered outside the five- or seven-year contract term. Recipients who are not direct parties to a contract executed before October 1, 2015, however, may not exercise options (a/k/a "piggybacking") on such contracts and apply the lower domestic content requirement. The assignment of options to a third party results in the third party and the vendor entering into a new contract after the effective date of the FAST Act, and therefore, the increased domestic content requirements for FY2018 and beyond will apply to vehicles delivered in those years.

State Purchasing Schedules. Some recipients purchase rolling stock from a State purchasing schedule. A State purchasing schedule is an arrangement that a State has established with multiple vendors in which those vendors agree to provide essentially an option to the State, and its subordinate governmental entities and others it might include in its programs, to acquire specific property or services in the future at established prices. Because the purchasing schedule does not commit the State to procuring a minimum number of vehicles, a "contract" does not exist until a State, recipient or sub-recipient enters into a purchase order with a vendor listed on the schedule.

Therefore, for purchase orders placed against State purchasing schedules before October 1, 2015, for the delivery of rolling stock in FY2018 and beyond, the increased domestic content requirements will not apply. For purchase orders placed against State schedules on or after October 1, 2015, for rolling stock that will be delivered in FY 2016 and 2017, the domestic content requirement must exceed 60%. For purchase orders placed against State schedules for rolling stock that will be delivered in FY 2018 and 2019, the domestic content must exceed 65%, and for purchase orders placed against State schedules for rolling stock that will be delivered in FY 2020 and beyond, the domestic content must exceed 70%.

FTA believes that this interpretation is consistent with the plain language of the statute, Congress' directive to increase the domestic content for vehicles produced in FY2018 or later, and principles of statutory construction.

Calculation of Domestic Content. The FTA will adjust the calculation for determining whether a component is of domestic origin under 49 CFR 661.11 to accommodate the increase in domestic content for FY2018 and beyond. Currently under 49 CFR 661.11(g), "for a component to be of domestic origin, more that 60 percent of the subcomponents of that component, by cost, must be of domestic origin, and the manufacture of the component must take place in the United States. If, under the terms of this part, a component is determined to be of domestic origin, its entire cost may be used in calculating the cost of domestic content of an end product."

Thus, for FY2018 and 2019, for a component to be of domestic content, more than 65 percent of the subcomponents of that component, by cost, must be of domestic origin, and for FY2020 and beyond, more than 70 percent of the subcomponents of the component must be of domestic content. The requirement that manufacture of the component take place in the United States still applies. Additionally, if a component is determined to be of domestic origin, its entire cost may be used in calculating the cost of content of an end product.

General Public Interest Waivers. FTA recognizes, however, that the FAST Act amendments to the rolling stock Buy America waiver may produce significant hardship for two categories of recipients and manufacturers: (1) Recipients who entered into contracts or placed purchase orders against State schedules between October 1, 2015 and December 4, 2015; and (2) recipients who have entered into contracts after December 4, 2015, as a result of solicitations for bids or requests for proposals that were advertised before December 4, 2015.

Under 49 U.S.C. 5323(j)(2)(A), the Administrator may waive the Buy America requirements if the Administrator finds that applying the Buy America requirements would be inconsistent with the public interest. "In determining whether the conditions exist to grant a public interest waiver, the Administrator will consider all appropriate factors on a case-by-case basis . . . When granting a public interest waiver, the Administrator shall issue a detailed written statement justifying why the waiver is in the public interest. The Administrator shall publish this justification in the **Federal Register**, providing the public with a reasonable time for notice and comment of not more than seven calendar days." 49 CFR 661.7(b).

In a separate notice published in today's **Federal Register**, FTA is seeking comment on a general public interest waiver. This public interest waiver is for the following categories of contracts: (1) For contracts entered into between the FAST Act's effective date and date of enactment (*i.e.*, between October 1, 2015 and December 4, 2015), the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered; and (2) for contracts entered into after December 4, 2015 as a result of solicitations for bids or requests for proposals that were advertised before December 4, 2015, the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered.

Recipients or vendors may apply to FTA for individual public interest waivers for contracts entered into after December 4, 2015, and others that do not fall within the scope of a general public interest waiver. A request for a public interest waiver should set forth the detailed justification for the proposed waiver, including information about the history of the procurement and the burden on the recipient and/or the industry in complying with the FAST Act. Public interest waivers should be narrowly tailored and FTA will not generally look favorably on waivers that provide for contracts that include the exercise of options for vehicles that will be delivered beyond FY2020. FTA will act expeditiously on public interest waiver requests that provide the information requested.

FTA seeks comment from all interested parties on the above policy statement. After consideration of the comments, FTA will publish a second notice in the **Federal Register** with a response to comments and noting any changes made to the policy statement as a result of the comments received.

Therese McMillan,
Acting Administrator.

[FR Doc. 2016–07837 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2016–0020]

Notice of Proposed Public Interest Waiver of Buy America Domestic Content Requirements for Rolling Stock Procurements in Limited Circumstances

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of proposed general public interest waiver and request for comments.

SUMMARY: The purpose of this notice is to articulate the Federal Transit Administration's (FTA) justification for waiving its Buy America requirements for rolling stock under certain limited circumstances because application of the increased domestic content requirements is inconsistent with public policy. The Fixing America's Surface Transportation (FAST) Act amended FTA's Buy America statute to include a phased increase in domestic content for rolling stock. The FAST Act was signed into law on December 4, 2015, but included an effective date of October 1, 2015. FTA proposes a public interest waiver for the following categories of contracts: (1) For contracts entered into between the FAST Act's effective date and date of enactment (*i.e.*, between October 1, 2015 and December 4, 2015), the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered; and (2) for contracts entered into after December 4, 2015 as a result of solicitations for bids or requests for proposals that were advertised before December 4, 2015, the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered. FTA is providing notice of this public interest waiver and seeks public comment. After consideration of the comments, FTA will issue a second **Federal Register** notice responding to comments and issuing final public interest waivers.

DATES: Comments must be received by April 13, 2016. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Please submit your comments by one of the following means, identifying your submissions by docket number FTA–2016–0020:

1. *Web site: http://www.regulations.gov.* Follow the instructions for submitting comments on the U.S. Government electronic docket site.

2. *Fax:* (202) 493–2251.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must make reference to the "Federal Transit Administration" and include docket number FTA–2016–0020. Due to the security procedures in effect since October 2011, mail received through the U.S. Postal Service may be subject to delays. Parties making submissions responsive to this notice should consider using an express mail firm to ensure the prompt filing of any submissions not filed electronically or by hand. Note that all submissions received, including any personal information therein, will be posted without change or alteration to *http://www.regulations.gov.* For more information, you may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000 (65 FR 19477), or you may visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Cecelia Comito, Assistant Chief Counsel, Office of the Chief Counsel, phone: (202) 366–2217 or email, *Cecelia.Comito@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The FAST Act, FTA's current authorizing legislation, amended the rolling stock waiver in 49 U.S.C. 5323(j)(2)(C) to provide for a phased increase in the domestic content for rolling stock for FY2018–FY2019 and FY2020 and beyond. As amended by the FAST Act, the domestic content for rolling stock increases over time from the current rate of "more than 60 percent" to "more than 70 percent" in FY2020 and beyond:

(j) Buy America.

(1) In general. The Secretary may obligate an amount that may be appropriated to carry out this chapter for a project only if the steel, iron, and manufactured goods used in the project are produced in the United States.

(2) Waiver. The Secretary may waive paragraph (1) of this subsection if the Secretary finds that:

* * * * *

(C) when procuring rolling stock (including train control, communication, traction power equipment, and rolling stock prototypes) under this chapter

(i) the cost of components and subcomponents produced in the United States

(I) for fiscal years 2016 and 2017, is more than 60 percent of the cost of all components of the rolling stock;

(II) for fiscal years 2018 and 2019, is more than 65 percent of the cost of all components of the rolling stock; and

(III) for fiscal years 2020 and each fiscal year thereafter, is more than 70 percent of the cost of all components of the rolling stock; and

(ii) final assembly of the rolling stock has occurred in the United States . . .

In a separate notice published in today's **Federal Register**, FTA is seeking comment on its proposed statement of policy regarding the implementation of the phased increase in domestic content for rolling stock under the FAST Act. FTA interprets the language in the FAST Act to require that if the date a recipient enters into a contract for rolling stock occurs after the effective date of the FAST Act, *i.e.*, October 1, 2015, then the new FAST Act provisions for rolling stock apply. Thus, contracts entered into after October 1, 2015 must provide that vehicles delivered in FY2018 and FY2019 have a domestic content of more than 65 percent, and that vehicles delivered in FY2020 and beyond must have a domestic content of more than 70 percent. These delivery provisions apply to contracts signed after the effective date of the FAST Act, *i.e.*, October 1, 2015, unless a waiver is granted.

II. Proposed Public Interest Waiver

With certain exceptions, FTA's "Buy America" requirements prevent FTA from obligating an amount that may be appropriated to carry out its program for a project unless "the steel, iron, and manufactured goods used in the project are produced in the United States." 49 U.S.C. 5323(j)(1). One such exception is where applying the Buy America requirements "would be inconsistent with the public interest." 49 U.S.C. 5323(j)(2)(A). After considering all appropriate factors on a case-by-case basis, 49 CFR 661.7(b), if FTA determines that the conditions exist to grant a public interest waiver, FTA will issue a detailed written statement justifying why the waiver is in the public interest, and will publish this justification in the **Federal Register**, providing the public with a reasonable time for notice and comment of not more than seven calendar days. 49 CFR 661.7(b).

Recipients who entered into rolling stock contracts prior to December 4, 2015, were required under existing Buy America law to procure vehicles with a domestic content of more than 60 percent, regardless of when the vehicle was delivered. Because rolling stock frequently cannot be delivered in a short time frame, recipients may enter into multi-year contracts for rolling stock, allowing for contracts up to five years for buses and up to seven years for railcars. 49 U.S.C. 5325(e). Thus, under existing law at the time of contracting, recipients were not prohibited from entering into contracts for vehicles that would be delivered in FY2018 and beyond.

Although the FAST Act was signed into law on December 4, 2015, Congress included an effective date of October 1, 2015. Application of the FAST Act's retroactive effective date to rolling stock contracts entered into between October 1, 2015 and December 4, 2015, would result in rendering those contracts ineligible for FTA funds for vehicles delivered in FY2018 and beyond. Without a waiver, recipients most likely would be required to cancel those contracts, and start the procurement process again.

"The inquiry into whether a statute operates retroactively demands a "commonsense, functional judgment about 'whether the new provision attaches new legal consequences to events completed before its enactment.'" *INS* v. *St. Cyr.*, 533 U.S. 289, 312 (2001) (quoting *Martin* v. *Hadix*, 527 U.S. 343, 357–358 (1999)). Additionally, "the mere promulgation of an effective date for a statute does not provide sufficient assurance that Congress specifically considered the potential unfairness that retroactive application would produce." *St. Cyr.*, 533 U.S. at 317. Thus, the decision to apply a statute retroactive should be guided by considerations of fair notice, reasonable reliance, and settled expectations.

Retroactive application of the FAST Act's increase in domestic content to contracts entered into between October 1, 2015 and December 4, 2015 would be inconsistent with the public interest. As noted in the FTA's *Best Practices Procurement Manual*, the procurement process for buses and railcars can be several years from drafting detailed specifications to contract award. Rail vehicle procurements are planned seven to ten years in advance of needed completion because several interdependent contracts may have to be awarded in order to accomplish the project. Bus procurements generally require at least three years of advance planning.

Depending on the complexity of the procurement, the time intervals typically required to accomplish rolling stock contract awards might include:

- One year advance planning before Request for Proposals (RFP) for the engineering services;
- Four months from RFP to award of the engineering services;
- Two years to prepare technical specifications;
- Three months from completion of specifications to system RFP;
- Six months from system RFP to award; and
- Three years for system construction.

The planning and design processes can change this schedule significantly.

All of this planning and work by the recipient is at tremendous cost to the recipient, and therefore, to the public, both in terms of money and the delayed acquisition of new transit vehicles. Additionally, preparation of a proposal or bid in response to a solicitation for vehicles is both time-consuming and costly for the manufacturers.

Application of the FAST Act's increased domestic content requirements to rolling stock procurements for which recipients have advertised solicitations for bids or requests for proposals prior to December 4, 2015 will be particularly burdensome for both the recipient and the manufacturer. FTA proposes a public interest waiver under these circumstances. These procurements are underway and a change in the domestic content will require recipients to amend their solicitations and specifications in order to include the FAST Act's increased domestic content requirements, which would result in substantial delay and increased costs, particularly for those recipients who are about to enter into contracts.

Accordingly, FTA proposes a public interest waiver for the following categories of contracts: (1) For contracts entered into between the FAST Act's effective date and date of enactment (*i.e.*, between October 1, 2015 and December 4, 2015), the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered; and (2) for contracts entered into after December 4, 2015 as a result of solicitations for bids or requests for proposals that were advertised before December 4, 2015, the increased domestic content requirements for FY2018 and beyond will not apply, regardless of when the vehicles are delivered.

This public interest waiver is limited to the parties to the contract only. Recipients who are not direct parties to the contract, however, may not exercise options (a/k/a "piggybacking") on such contracts and take advantage of the lower domestic content requirement. The assignment of options to a third party results in the third party and the vendor entering into a new contract after the effective date of the FAST Act, and therefore, the increased domestic content requirements for FY2018 and beyond will apply to vehicles delivered in those years.

Recipients or vendors may apply to FTA for individual public interest waivers for contracts entered into after December 4, 2015, and others that do not fall within the scope of this general public interest waiver. A request for a public interest waiver should set forth the detailed justification for the proposed waiver, including information about the history of the procurement and the burden on the recipient and/or the industry in complying with the FAST Act. Public interest waivers should be narrowly tailored and FTA will not generally look favorably on waivers that provide for contracts that include the exercise of options for vehicles that will be delivered beyond FY2020. FTA will act expeditiously on public interest waiver requests that provide the information requested.

FTA seeks comment from all interested parties on the above public interest waiver. After consideration of the comments, FTA will publish a second notice in the **Federal Register** with a response to comments and noting any changes made to the public interest waiver as a result of the comments received.

Therese McMillan,
Acting Administrator.

[FR Doc. 2016–07836 Filed 4–5–16; 8:45 am]
BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0104; Notice 2]

JLG Industries, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: JLG Industries, Inc. (JLG) has determined that certain JLG Triple-L utility trailers do not fully comply with paragraph S4.3.5 of Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less*. JLG filed a report dated July 16, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. JLG then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

FOR FURTHER INFORMATION CONTACT: For further information on this decision contact Stuart Seigel, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), Telephone (202) 366–5287, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. JLG's Petition

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, JLG submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of JLG's petition was published, with a 30-day public comment period, on November 21, 2014, in the **Federal Register** (79 FR 69550). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/*. Then follow the online search instructions to located docket number "NHTSA–2014–0104."

II. Trailers Involved

Affected are approximately 2,940 JLG Triple-L utility trailers with a GVWR of less than 10,000 lbs. that were manufactured between August 2005 and July 2014.

III. Noncompliance

JLG explains that the noncompliance is that the tire and loading information placard does not contain the words "The weight of the cargo should never exceed XXX kilograms or XXX pounds" as required by paragraph S4.3.5 of FMVSS No. 110.

IV. Rule Text

Paragraph S4.3.5 of FMVSS No. 110 requires in pertinent part:

> S4.3.5 *Requirements for trailers.* Each trailer, except for an incomplete vehicle, must show the information specified in S4.3 (c) through (g), and may show the information specified in S4.3 (h) and (i), on a placard permanently affixed proximate to the certification label specified in 49 CFR part 567. Additionally, each trailer must on its placard contain a cargo capacity statement expressed as "The weight of cargo should never exceed XXX kilograms or XXX pounds" in the same location on the placard specified for the "vehicle capacity weight" statement required by the standard. . . .

V. Summary of JLG's Analyses

JLG stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) With regard to trailers JLG states that there is no need to account for passenger weight when considering cargo weight because there are no designated seating positions on the trailer and all of the weight capacity is designated towards cargo. JLG also believes that providing the maximum load capacity for the trailer therefore provides the same information as providing the maximum weight of the cargo.

(B) Although the Tire and Loading Information labels on the subject trailers do not contain the statement set forth in S4.3.5, the same information is provided on a separate label in the vicinity of the Tire and Loading Information label. That label states that the "Max Load Capacity xxxx lbs" and further instructs the operator to "center load on deck." It also draws attention to the maximum carrying load of the trailer and ensures that drivers loading the trailer are aware of the maximum load capacity the trailer can carry—the precise information the regulatory text intends to be conveyed.

JLG has additionally informed NHTSA that it has corrected the noncompliance so that all future production trailer Tire and Loading Information labels will comply with FMVSS No. 110.

In summation, JLG believes that the described noncompliance of the subject trailers is inconsequential to motor vehicle safety, and that its petition, to exempt JLG from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA'S Decision

NHTSA's Analysis: NHTSA has reviewed JLG's analyses and justification for an inconsequential noncompliance determination for the affected 2940 utility trailers with incorrect wording on the Tire and Loading Information placard. Specifically, the required wording "The weight of the cargo should never exceed XXXX kg or XXXX lbs." is replaced with "Max. Load Capacity XXXX lbs." on a separate label placed in the vicinity of the Tire and Loading Information placard. The wording of these two labels as described below have an equivalent meaning and as such there is little to no risk to motor vehicle safety. The cargo capacity statement or "vehicle capacity weight" statement required by FMVSS No. 110 is defined as "the rated cargo and luggage load plus 68 kilograms times the vehicle's designated seating capacity." As these trailers do not carry passengers and therefore have no designated seating positions, the maximum load capacity for the trailer as specified on the JLG trailer label is functionally equivalent to the cargo capacity value that should be specified on the FMVSS No. 110 placard. There is no confusion for the trailer user as to the weight that can be carried on the trailer. In addition, the absence of the loading information in kilograms is not likely to be problematic for users of these trailers.

NHTSA's Decision: In consideration of the foregoing, NHTSA finds that JLG has met its burden of persuasion that the subject FMVSS No. 110 noncompliance in the affected vehicles is inconsequential to motor vehicle safety. Accordingly, JLG's petition is hereby granted and JLG is consequently exempted from the obligation of providing notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject trailers that JLG no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant trailers under their control after JLG notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2016–07872 Filed 4–5–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8582–CR

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8582–CR, Passive Activity Credit Limitations.

DATES: Written comments should be received on or before June 6, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Allan Hopkins, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Allan.M.Hopkins@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Passive Activity Credit Limitations.

OMB Number: 1545–1034.

Form Number: 8582–CR.

Abstract: Under Internal Revenue Code section 469, credits from passive activities, to the extent they do not exceed the tax attributable to net passive income, are not allowed. Form 8582–CR is used to figure the passive activity credit allowed and the amount of credit to be reported on the tax return.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, and farms.

Estimated Number of Respondents: 300,000.

Estimated Time per Respondent: 14 hr., 53 min.

Estimated Total Annual Burden Hours: 2,370,600.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: March 30, 2016.

Allan Hopkins,

Tax Analyst.

[FR Doc. 2016–07822 Filed 4–5–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Tax Design Challenge; Requirements and Procedures; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice; correction.

SUMMARY: The Internal Revenue Service published a document in the **Federal Register** of March 22, 2016, concerning the Tax Design Challenge, a crowdsourcing competition, with cash prizes, that the IRS is hosting to begin reimagining the taxpayer experience of the future. The document omitted a requirement for participation.

FOR FURTHER INFORMATION CONTACT: Christopher Daggett, 503–330–6311 or Michael Lin, 202–317–6381.

Correction

In the **Federal Register** of March 22, 2016, in FR Doc. 2016–06432, on page 15414, in the first column, replace the eight numbered eligibility requirements with nine requirements, as follows:

(1) Must register to participate in the Challenge under the rules promulgated by the Internal Revenue Service.

(2) Must comply with all the requirements under this section.

(3) Must be at least 18 years old at the time of submission.

(4) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(5) Shall not be a Federal entity or Federal employee acting within the scope of their employment.

(6) Shall not be an employee of the Internal Revenue Service or the Mortgage Bankers Association ("the Cosponsor").

(7) Shall not be affiliated with any judge on the review panel. In the case of a private entity, this means that no judge currently serves as a director, officer, or employee of the entity. In the case of a private individual, the individual shall not have a close family or professional relationship with any judge.

(8) Federal grantees may not use Federal funds to develop Challenge applications unless consistent with the purpose of their grant award.

(9) Federal contractors may not use Federal funds from a contract to develop Challenge applications or to fund efforts in support of a Challenge submission.

Dated: April 1, 2016.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2016–07858 Filed 4–5–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nominations for Appointment to the Advisory Committee on Cemeteries and Memorials

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA), National Cemetery Administration (NCA), is seeking nominations of qualified candidates to be considered for appointment as a member of the Advisory Committee on Cemeteries and Memorials (herein-after in this section referred to as "the Committee"). The Committee was established pursuant to 38 U.S.C. 2401 to advise the Secretary of VA with respect to the administration of VA national cemeteries, soldiers' lots and plots, which are the responsibility of the Secretary, the erection of appropriate memorials and the adequacy of Federal burial benefits.

DATES: Nominations of qualified candidates are being sought to fill upcoming vacancies on the Committee. Nominations for membership on the Committee must be received no later than 5:00 p.m. EST on May 31, 2016.

ADDRESSES: All nominations should be mailed to National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW. (43A2), Washington, DC 20420, or faxed to (202) 632–7910.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Nacincik, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW. (43A2), Washington, DC 20420, telephone (202) 632–8013. A copy of Committee charter and list of the current membership can be obtained by contacting Mr. Nacincik or by accessing the Web site managed by NCA at: *http://www.cem.va.gov/cem/about/advisory_committee.asp.*

SUPPLEMENTARY INFORMATION: The Advisory Committee on Cemeteries and Memorials (ACCM) was established pursuant to 38 U.S.C. 2401 to advise the Secretary of VA with respect to the administration of VA national cemeteries, soldiers' lots and plots, which are the responsibility of the Secretary, the erection of appropriate memorials and the adequacy of Federal burial benefits. The Committee responsibilities include:

(1) Advising the Secretary on VA's administration of burial benefits and the selection of cemetery sites, the erection of appropriate memorials, and the adequacy of Federal burial benefits;

(2) Providing to the Secretary and Congress periodic reports outlining recommendations, concerns, and observations on VA's delivery of these benefits and services to Veterans;

(3) Meeting with VA officials, Veteran Service Organizations, and other stakeholders to assess the Department's efforts in providing burial benefits and outreach on these benefits to Veterans and their dependents;

(4) Undertaking assignments to conduct research and assess existing burial and memorial programs; to examine potential revisions or expansion of burial and memorial programs and services; and to provide advice and recommendations to the Secretary based on this research.

NCA is requesting nominations for upcoming vacancies on the Committee. The Committee is composed of up to twelve members and several ex-officio members.

The members of the Committee are appointed by the Secretary of Veteran Affairs from the general public, including but not limited to:

(1) Veterans or other individuals who are recognized authorities in fields pertinent to the needs of Veterans;

(2) Veterans who have experience in a military theater of operations;

(3) Recently separated service members;

(4) Officials from Government, non-Government organizations (NGOs) and industry partners in the provision of memorial benefits and services, and outreach information to VA beneficiaries.

The Secretary shall determine the number, terms of service, and pay and allowances of members of the Committee appointed by the Secretary, except that a term of service of any such member may not exceed three years. The Secretary may reappoint any such member for additional terms of service.

To the extent possible, the Secretary seeks members who have diverse professional and personal qualifications, including but not limited to prior military experience and military deployments, experience working with Veterans, and experience in large and complex organizations, and subject matter expertise in the areas described above. We ask that nominations include information of this type so that VA can ensure diverse Committee membership.

Requirements for Nomination Submission: Nominations should be typed (one nomination per nominator). Nomination package should include:

(1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.* specific attributes which qualify the nominee for service in this capacity), and a statement from the nominee indicating the willingness to serve as a member of the Committee;

(2) The nominee's contact information, including name, mailing address, telephone numbers, and email address;

(3) The nominee's curriculum vitae; and

(4) A summary of the nominee's experience and qualifications relative to the membership considerations described above.

Individuals selected for appointment to the Committee shall be invited to serve a two-year term. Committee members will receive a stipend for attending Committee meetings, including per diem and reimbursement for travel expenses incurred. The Department makes every effort to ensure that the membership of VA federal advisory committees is diverse in terms of points of view represented and the committee's capabilities. Appointments to this Committee shall be made without discrimination because of a person's race, color, religion, sex, sexual orientation, gender identify, national origin, age, disability, or genetic information. Nominations must state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude membership. An ethics review is conducted for each selected nominee.

Dated: March 31, 2016.

Jeffrey M. Martin,

Office Program Manager, Office of Regulation and Policy Management.

[FR Doc. 2016–07826 Filed 4–5–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 81 Wednesday,
No. 66 April 6, 2016

Part II

Department of the Interior

Fish and Wildlife Service
50 CFR Part 17

Department of Commerce

National Oceanic and Atmospheric Administration
50 CFR Parts 223 and 224
Endangered and Threatened Wildlife and Plants; Final Rule To List Eleven Distinct Population Segments of the Green Sea Turtle *(Chelonia mydas)* as Endangered or Threatened and Revision of Current Listings Under the Endangered Species Act; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 120425024–6232–06]

RIN 0648–XB089

Endangered and Threatened Wildlife and Plants; Final Rule To List Eleven Distinct Population Segments of the Green Sea Turtle (Chelonia mydas) as Endangered or Threatened and Revision of Current Listings Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce; United States Fish and Wildlife Service (USFWS), Interior.

ACTION: Final rule.

SUMMARY: NMFS and USFWS issue a final rule to list 11 distinct population segments (DPSs) of the green sea turtle (*Chelonia mydas;* hereafter referred to as the green turtle) under the Endangered Species Act (ESA). Based on the best available scientific and commercial data, and after considering comments on the proposed rule, we have determined that three DPSs are endangered species and eight DPSs are threatened species. This rule supersedes the 1978 final listing rule for green turtles. It applies the existing protective regulations to the DPSs. Critical habitat is not determinable at this time but will be proposed in a future rulemaking. In the interim, the existing critical habitat designation (*i.e.,* waters surrounding Culebra Island, Puerto Rico) remains in effect for the North Atlantic DPS.

DATES: This final rule is effective May 6, 2016.

ADDRESSES: Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Room 13535, Silver Spring, MD 20910; or U.S. Fish and Wildlife Service, North Florida Ecological Services Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256. The final rule, list of references, and other materials relating to this determination can be found at: *http://www.nmfs.noaa.gov/pr/species/turtles/green.htm.*

FOR FURTHER INFORMATION CONTACT: Jennifer Schultz, NMFS (ph. 301–427–8443, email *jennifer.schultz@noaa.gov*), or Ann Marie Lauritsen, USFWS (ph. 904–731–3032, email *annmarie_lauritsen@fws.gov*). Persons who use a Telecommunications Device for the Deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, and 7 days a week.

SUPPLEMENTARY INFORMATION:

Background

On July 28, 1978, NMFS and USFWS, collectively referred to as the Services, listed the green turtle under the ESA (43 FR 32800). Pursuant to the authority that the statute provided, and prior to the current statutory definition of "species" that includes DPSs, we listed the species as threatened, except for the Florida and Mexican Pacific coast breeding populations, which we listed as endangered. We published recovery plans for U.S. Atlantic (NMFS and USFWS, 1991) and U.S. Pacific (including the East Pacific; 63 FR 28359, May 22, 1998; NMFS and USFWS, 1998) populations of the green turtle (*http://www.nmfs.noaa.gov/pr/recovery/plans.htm*). NMFS designated critical habitat for the species to include waters surrounding Culebra Island, Puerto Rico, and its outlying keys (63 FR 46693, September 2, 1998).

On February 16, 2012, we received a petition from the Association of Hawaiian Civic Clubs to identify the Hawaiian green turtle population as a DPS and "delist" it. On August 1, 2012, NMFS, with USFWS concurrence, determined that the petition presented substantial information indicating that the petitioned action may be warranted (77 FR 45571). Our 5-year review (NMFS and USFWS, 2007) also recommended a review of the status of the species, in light of significant new information since its listing and in accordance with our DPS joint policy (61 FR 4722, February 7, 1996). We convened a Status Review Team, green turtle and ESA experts within the Services, who conducted a comprehensive status review of the species and published their findings as the "Status Review of the Green Turtle (*Chelonia mydas*) under the Endangered Species Act" (Seminoff *et al.,* 2015; hereafter referred to as the Status Review Report and available at *http://www.nmfs.noaa.gov/pr/species/Status%20Reviews/green_turtle_sr_2015.pdf*). The Status Review Report was peer-reviewed by 15 independent scientists with expertise in green turtle biology, genetics, endangered species policy, or related fields. We used the Status Review Report and additional information, which together provided the best available scientific and commercial data, to make our listing determinations.

On March 23, 2015, we published the 12-month finding on the petition and proposed rule (80 FR 15271). We proposed to remove the existing ESA listings from 1978 and, in their place, list three endangered (Mediterranean, Central West Pacific, and Central South Pacific) and eight threatened (North Atlantic, South Atlantic, Southwest Indian, North Indian, East Indian-West Pacific, Southwest Pacific, Central North Pacific, and East Pacific) DPSs. We opened a 90-day comment period on the proposed rule and extended this comment period three times until September 25, 2015, for a total of 187 days (*i.e.,* just over 6 months).

Listing Determinations Under the ESA

Section 4(a)(1) of the ESA requires us to determine by regulation whether "any species is an endangered species or a threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence" (16 U.S.C. 1533(a)(1); hereafter, the section 4(a)(1) factors). Section 3 of the ESA defines a "species" as "any subspecies of fish or wildlife or plants, and any DPS of any species of vertebrate fish or wildlife which interbreeds when mature" (16 U.S.C. 1532(16)). Section 3 of the ESA further defines an "endangered species" as "any species which is in danger of extinction throughout all or a significant portion of its range" and a "threatened species" as one "which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range" (16 U.S.C. 1532(6), (20)). The U.S. District Court for the District of Columbia noted that Congress included "a temporal element to the distinction between the categories of endangered and threatened species." *In Re Polar Bear Endangered Species Act Listing and § 4(d) Rule Litigation,* 794 F. Supp.2d 65, 89 n. 27. (D.D.C. 2011). Thus, we interpretlan "endangered species" to be one that is presently in danger of extinction. A "threatened species," on the other hand, is not presently in danger of extinction, but is likely to become so within the foreseeable future (*i.e.,* at a later time). In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species may be in danger of extinction, either presently (endangered) or within the foreseeable future (threatened). As we explained in the proposed rule, the foreseeable future applied in a particular listing determination must take into account the life history of the species, habitat characteristics, availability of data, particular threats under consideration, the ability to predict those threats, and the reliability of forecasts of changes in the species' status in response to the threats. See also "The Meaning of 'Foreseeable Future' in Section 3(20) of the Endangered Species Act," (M–37021, U.S. Department of the Interior, Office of the Solicitor, January 16, 2009).

The ESA does not define "distinct population segment," but our 1996 joint policy identifies three elements that must be considered when identifying a DPS: (1) The discreteness of the population segment in relation to the remainder of the species to which it belongs; (2) the significance of the population segment to the species to which it belongs; and (3) the population segment's conservation status (*i.e.,* endangered or threatened; 61 FR 4722, February 7, 1996). Section 4(c)(1) of the ESA requires us to revise the lists of threatened and endangered species to reflect recent determinations to list, remove, or change the status of a species (16 U.S.C. 1533(c)(1)). Section 4(b)(1)(A) requires us to make such determinations "solely on the basis of the best scientific and commercial data available . . . after conducting a review of the status of the species" and after considering conservation efforts (16 U.S.C. 1533(b)(1)(A)). This can be thought of as consisting of two steps: The status review and the listing determinations.

As we described more fully in the proposed rule, to identify potential DPSs, the Status Review Team members gathered the best available scientific and commercial data on green turtles. They evaluated the discreteness and significance of population segments. For each potential DPS, they described the demographic parameters that influence population persistence (*i.e.,* abundance, growth rate or trend, spatial structure or connectivity, and diversity or resilience; McElhany *et al.,* 2000) and analyzed the section 4(a)(1) factors (16 U.S.C. 1533(a)(1)). For their analyses, the Status Review Team used a foreseeable future of 100 years, which represents approximately three generations of green turtles and is often used for projections of extinction risk in recovery plans and status reviews for long-lived species, such as whales and sea turtles (Angliss *et al.,* 2002; NMFS, 2005, 2010, 2011; Conant *et al.,* 2009; Seminoff *et al.,* 2015). To assess extinction risk, the Status Review Team used a critical risk threshold (*i.e.,* quasi-extinction), which they defined as being met where a DPS, "has such low abundance, declining trends, limited distribution or diversity, and/or significant threats (untempered by significant conservation efforts) that the DPS would be at very high risk of extinction with little chance for recovery" (Seminoff *et al.,* 2015). The Status Review Team did not consider the potential loss of ESA protections (*i.e.,* potential determination not to list a DPS) in their analyses. They incorporated all information and analyses into the Status Review Report.

We reviewed the Status Review Report and concluded that it provided the best available scientific and commercial data on the identification of DPSs, demographic parameters, and section 4(a)(1) factors, with two exceptions. First, in evaluating the extinction risk of a DPS, we cannot assume the retention of ESA protections, which would no longer apply if a DPS was not listed under the ESA. Second, the critical risk threshold (*i.e.,* quasi-extinction) does not directly correlate with the ESA definitions of "endangered" and "threatened" because it requires a condition worse than endangered (*i.e.,* "very high risk of extinction") and essentially precludes recovery (*i.e.,* "little chance for recovery"). The latter is contrary to the fundamental purpose of the ESA, which is to conserve threatened and endangered species. Section 3 of the ESA defines conservation as "to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the ESA] are no longer necessary" (16 U.S.C. 1532); our implementing regulations add "*i.e.,* the species is recovered" (50 CFR 424.02). Therefore, we did not use the critical risk threshold to make our listing determinations.

To make the listing determinations, we used the best available scientific and commercial data on the green turtle, which are summarized in the Status Review Report and incorporated herein. We applied information from the Status Review Report on the identification of DPSs, demographic parameters, and section 4(a)(1) factors, but we did not apply the critical risk threshold. Instead, we directly evaluated the section 4(a)(1) factors in the context of the demographic parameters and considered the potential loss of ESA protections that would result if we did not list a DPS as threatened or endangered under the ESA. After considering conservation efforts by States and foreign nations to protect the DPS, as required under section 4(b)(1)(A), we proposed listing determinations based on the statutory definitions of endangered and threatened species (80 FR 15271, March 23, 2015). To make our final listing determinations, we reviewed all information provided during the 6-month public comment period and additional scientific and commercial data that became available since the publication of the proposed rule. However, this additional information merely supplemented, and did not differ significantly from, the information presented in the proposed rule. We received no significant new information that would cause us to change our listing determinations. With this rule, we finalize our proposed listing determinations.

Summary of Comments

We solicited comments on the proposed rule from all interested parties (80 FR 15271, March 23, 2015). Specifically, we requested information regarding: (1) Historical and current population status and trends; (2) historical and current distribution; (3) migratory movements and behavior; (4) genetic population structure; (5) current or planned activities that may adversely affect green turtles; (6) conservation efforts to protect green turtles; and (7) our extinction risk analysis and findings. We considered all comments received, which included 905 comments from the public, government agencies, the scientific community, industry, and environmental organizations. The majority of comments (over 800) expressed support for the proposed listings. Some commenters requested that all DPSs be listed as endangered, and some commenters disagreed with the proposed status of one or more DPSs. We summarize all comments below by first addressing topics that apply to multiple DPSs; we then address comments specific to a particular DPS.

Comments on Topics That Apply to Multiple DPSs

Comment 1: We received several comments regarding public engagement. We received several requests for public hearings in Hawaii, Guam, the Commonwealth of the Northern Mariana Islands (CNMI), and American Samoa. One commenter stated that there has been inadequate public engagement.

Response: We held public hearings in Hawaii, Guam, CNMI, and American Samoa, exceeding our regulatory obligation of holding at least one public hearing (50 CFR 424.16(c)(1)). Further, we encouraged maximum public participation by extending the 90-day public comment period three times, for a total of 6 months. We made all relevant information (both as to the substance of the proposed rule and opportunities for public participation) available on our Web pages, notified the petitioner via phone and email, provided informational meetings via internet and telephone (*i.e.,* "webinars"), and addressed questions on the proposed rule via phone and email. We have thus facilitated considerable public engagement, which has been sufficient to inform our final determinations.

Comment 2: We received several comments on our approach for identifying DPSs. One commenter stated that while the DPS concept started under the ESA, it is now used generally in the scientific literature. The commenter also asked whether alternatives were considered, such as combining the North and South Atlantic DPSs and combining Indian Ocean DPSs, for ease of application of the ESA. Two commenters requested a discussion of the potential limitations of mitochondrial DNA (mtDNA) for identifying DPSs, including limited sequencing information, maternal inheritance, and neutral genetic diversity. One commenter requested clarification on our evaluation of genetic population structure at nesting sites, and one commenter asked where green turtles mate. One commenter agreed with the designations, stating that the designation of DPSs has little potential for negative consequences, whereas the over-generalized species listing will continue to yield non-individualized conservation methods and runs the risk of greater population losses. One commenter provided additional scientific information in support of the DPSs; the commenter stated that the DPSs may require reevaluation in the future as new information becomes available.

Response: For a detailed explanation of the application of our DPS policy to the green turtle, please see the Status Review Report and proposed rule. We provide a short summary in the previous section entitled, *Listing Determinations under the ESA.*

Though the term "distinct population segment" may be used generally in the scientific literature, our use of the term throughout the proposed and final rules refers to the legal term, "distinct population segment," as used specifically in the statute and our binding policy, which we promulgated after reviewing public comment (16 U.S.C. 1532 (16); 61 FR 4722, February 7, 1996). The Status Review Team considered other potential DPSs, including 17 regional management units identified by Wallace *et al.* (2010); however, the criteria for those management units differed from those outlined under our DPS policy (61 FR 4722, February 7, 1996). We did not combine or separate DPSs to facilitate application of the ESA because we concluded it was more important to retain a consistent approach to all DPSs. We agree that the identification of DPSs will allow us to provide the most appropriate and effective conservation strategy for each DPS; however, Congress instructs us to exercise our authority with regard to DPSs "sparingly and only when the biological evidence indicates that such action is warranted" (S. Rept. 96–151 (1979)).

Our DPS policy requires a DPS be "discrete" and "significant" (61 FR 4722, February 7, 1996). To evaluate discreteness, the Status Review Team considered tagging and telemetry, morphology, oceanographic and ecological features, and genetic data. The genetic data included previously published studies of biparentally (nuclear DNA) and maternally (mtDNA) inherited neutral genetic markers (Seminoff *et al.,* 2015). In addition, the Status Review Team considered a global phylogenetic analysis based on nearly 400 base pairs of mtDNA sequence data from approximately 4,400 turtles sampled at 105 nesting sites (Jensen and Dutton, NMFS, unpublished data; M. Jensen, National Research Council (NRC), pers. comm., 2013). Samples collected at nesting sites provided the best available data due to plenitude (*i.e.,* samples are often collected during nesting site surveys) and relevance, *i.e.,* the species is somewhat organized around these sites, with females (and to a lesser extent males) returning to the waters off their natal beaches to mate (Balazs, 1980; Dizon and Balazs, 1982; Bowen *et al.,* 1992; Karl *et al.,* 1992). Though mtDNA data do not reflect male-mediated gene flow, and additional sequencing may provide increased resolution in some cases (*e.g.,* Dutton *et al.,* 2014b), they remain the best available scientific data to detect marked genetic separation (*i.e.,* discreteness) among population segments throughout the range of the species.

The Status Review Team also considered the significance of the population segment to the species. Each DPS was determined to be significant because of its unique ecological setting or because its loss would result in a significant gap in the range of the species. In addition, some DPSs differed markedly from others in their genetic characteristics, likely due to exposure to different selective pressures and generations of reproductive isolation.

We reviewed, considered, and incorporated as appropriate scientific and commercial data that were not previously included in the Status Review Report or proposed rule; however, this additional information did not change our identification of any DPS. Scientific or commercial data that become available after the publication of this rule will be reviewed at a later date as appropriate (*e.g.,* during a 5-year review).

Comment 3: We received several comments regarding the general process for making our listing determinations. One commenter asked why some DPSs were proposed to be listed as endangered and others as threatened. Some commenters stated that DPSs should be delisted or listed as threatened (rather than endangered) to reward conservation efforts. Several commenters asked why we did not use the population viability analyses (PVAs) or critical risk threshold from the Status Review Report. One commenter stated that the listing determinations must be based on the best available science, including the information provided in the Status Review Report and any additional information available. One commenter inquired about our approach to uncertainty when making our listing determinations.

Response: Please see the previous section entitled, *Listing Determinations under the ESA,* which describes the listing process, the difference between endangered and threatened species, the sources of the best available data, and the reasons that we did not apply the critical risk threshold. Regarding the comment that DPSs should be delisted or listed as threatened to reward conservation efforts, the ESA requires us to base our listing determinations solely on the best available scientific and commercial data, after taking into account efforts to protect species (16 U.S.C. 1533(b)(1)(A)). We review conservation efforts, as required under the statute, to determine whether they will be implemented and effective in ameliorating threats to the species. While the existence of such efforts can avoid the need for an ESA listing, that determination is based on whether the best available data allow us to conclude that those efforts improve the status of the species, not on whether a party should be "rewarded" for their efforts.

We used information from the Status Review Report on the demographic parameters and section 4(a)(1) factors to make our listing determinations. The

Status Review Team used PVAs as one component in the consideration of population trends (*i.e.*, one of the demographic parameters). They performed PVAs on nesting sites if adequate data were available; therefore, the results did not apply to the entire DPS, and PVAs were not available for all DPSs. The required assumptions of the PVAs (*i.e.*, constant environmental and anthropogenic pressures) are not likely to be met. The PVAs did not incorporate the section 4(a)(1) factors, including climate change, or the potential loss of ESA protections. For these reasons, we did not base our listing determinations on the PVAs; however, we included the PVAs as one measure of trends when considering the demographic parameters.

Regarding our treatment of uncertainty, it is important to note that the best available scientific and commercial data are not required to be free from uncertainty. We identified uncertainties in the demographic parameters and section 4(a)(1) factors throughout the proposed rule. Nevertheless, we did not base any listing determination solely on uncertain demographic parameters or section 4(a)(1) factors.

Comment 4: We received several comments on demographic parameters. One commenter asked us to define "low" total nester abundance. Several commenters stated that they observe more foraging or in-water green turtles, now compared with previous years.

Response: Our demographic parameters include the total nester abundance, as described in the Status Review Report. Total nester abundance ranges from an estimated 404 to 992 nesting females for the Mediterranean DPS to an estimated 167,424 nesting females for the North Atlantic DPS. As a general guide, we considered total nester abundance to be low if there were fewer than 10,000 nesting females. Total nester abundance provides one measure of resilience. All else being equal, small populations are at greater risk of extinction than large populations primarily because of depensation, deterministic density effects, environmental variation, genetic processes, demographic stochasticity, ecological feedback, and catastrophes (McElhany *et al.*, 2000).

The estimates of total nester abundance and trends were based on quantitative surveys at nesting beaches; however, qualitative data on nesting sites were provided for each DPS. To evaluate the demographic parameters, the Status Review Team did not rely on qualitative estimates of abundance at foraging habitats or other areas. Such areas often include many juvenile turtles, which are characterized by lower survival rates relative to adults (Halley *et al.*, in review) and are less likely to contribute to population productivity (*i.e.*, resilience). Furthermore, observational data are often subject to bias based on the observer's prior experience. Population declines in many DPSs occurred decades or centuries ago. Under this shifting baseline, an observer may conclude that there are "more" turtles relative to their earlier, personal observations of the depleted population (*i.e.*, prior to conservation efforts); however, this conclusion likely underestimates the population's pre-exploitation abundance (Pauly 1995; Bowen and Avise, 1995; Jackson 1997; Bjorndal *et al.*, 1999; McClenachan *et al.*, 2006; Kittinger *et al.*, 2013). For these reasons, we conclude that the quantitative surveys at nesting beaches provide the best available scientific data to assess abundance and resilience for each DPS.

Comment 5: Two commenters stated that U.S. sea turtle population assessments rely too heavily on estimates of nesting females, citing the Assessment of Sea Turtle Status and Trends (NRC, 2010).

Response: The Status Review Team evaluated the section 4(a)(1) factors throughout the range of each DPS, including at nesting beaches, foraging areas, migratory corridors, and developmental habitats. To evaluate demographic parameters, the Status Review Team used total nester abundance and nesting trends, which are the best available scientific data and most relevant to the resilience of a DPS, as described in the response to *Comment 4*. Though the NRC report recommends collecting data at life stages "in addition to adult females" (NRC, 2010), the ESA requires us to base our listing determinations on the best available scientific and commercial data, a standard which does not require the collection of new data. As explained above, we have determined that data on nesting females are the best available scientific data.

Comment 6: We received many general comments on our analyses of the section 4(a)(1) factors. Many commenters stated that Fibropapillomatosis (FP) presents a large, and in some DPSs increasing, threat; however, two commenters stated that FP does not pose a threat to green turtles. One commenter requested that we distinguish between native and non-native predators. One commenter indicated that we did not give enough weight to unusual mortality events (UMEs), explaining that it would take only one algal bloom, oil spill, or other event to kill hundreds or thousands of turtles in a short period of time. One commenter indicated that we needed to make our oceans safer for turtles by eliminating longline fishing, banning plastics, and enforcing harassment and litter laws on beaches. One commenter identified snorkelers and divers as an additional threat to sea turtles directly or indirectly via threats to coral or seagrass (Meadows, 2004; Landry and Taggart, 2010). One commenter provided additional scientific information in support of our analyses of the section 4(a)(1) factors.

Response: The following response applies to general comments on the section 4(a)(1) factors for all DPSs; however, please see *Comments 7* and *8* for our responses regarding general comments on harvest and climate change, respectively. We reviewed, considered, and incorporated as appropriate scientific and commercial data that was not previously included in the Status Review Report or proposed rule.

The ESA requires us to determine whether any species is endangered or threatened because of any one or a combination of the section 4(a)(1) factors, including disease or predation (16 U.S.C. 1533 (a)(1)(C)). It does not distinguish between native or non-native predators; however, we included this information where available. FP is a disease that causes tumors in sea turtles. In 2015, NMFS hosted the International Summit on Fibropapillomatosis of Marine Turtles: Global Status, Trends, and Population Impacts. NMFS (in progress) summarized the current state of FP knowledge and concluded that FP has population level impacts because it generally results in reduced survivorship; however, some turtles recover from FP (Hirama, 2001; Hirama and Ehrhart, 2007). Therefore, we included FP in our analyses of section 4(a)(1) factors and considered the best available data on the incidence and expression of the disease for each DPS.

We considered the inadequacy of existing regulatory mechanisms for each DPS. For some DPSs, this included identification of inadequate harassment and pollution laws, due to lack of implementation and enforcement.

We evaluated other natural or manmade factors that affect the DPSs' continued existence. Plastics and other discarded materials (*i.e.*, marine debris) often entangle or are ingested by green turtles (*e.g.*, Schuyler *et al.*, 2014) and are a significant source of mortality in some DPSs. We considered algal blooms, oil spills, and cold stunning, which may result in UMEs. The impact of a UME is often dependent on the demographic factors of the DPS. For example, the North Atlantic DPS, with its high abundance and increasing trends, has exhibited resilience during recent UMEs caused by cold stunning (Seminoff *et al.*, 2015). In response to the public comment, we considered the potential impacts of snorkelers, which may damage coral reefs or seagrass beds (Landry and Taggart, 2010), cause green turtles to surface more frequently (Meadows, 2004), or alter turtles' foraging success; however, we are not aware of information demonstrating population-level impacts, which are likely to be small.

In summary, we considered each of the section 4(a)(1) factors for each DPS, including disease or predation, the inadequacy of existing regulatory mechanisms, and other natural or manmade factors. The information provided on FP, predation, harassment, pollution, plastics, UMEs, and snorkelers does not represent significant new information and does not change our proposed listing determinations.

Comment 7: We received several comments on the harvest of turtles and eggs. Several commenters, including Senator Palacios (CNMI) and the CNMI Department of Lands and Natural Resources, requested that the Services recognize and allow cultural harvest of green turtles. Some commenters suggested farming green turtles for such purposes. Some commenters requested take exemptions similar to those for Alaskan Natives or Tribes (in regards to threatened salmon). Some commenters stated that green turtles were once used for food and traditional ceremonies in Guam, CNMI, and Hawai'i. Two commenters explained that Federal regulations prohibiting such take became effective in 1976, when CNMI became a Commonwealth of the United States (Pub. L. 94–241, 90 Stat. 263 (1976)). One commenter stated that most people in CNMI have no tolerance for the disturbance and taking of the green turtle. Several commenters opposed harvest for any purpose, citing overexploitation as a threat.

Response: The take of endangered species is prohibited under section 9 of the ESA. Longstanding protective regulations apply the section 9 prohibitions to threatened sea turtles (50 CFR 17.42(b)(1); 50 CFR 223.205). These regulations remain in effect and are beyond the scope of this rulemaking. Under the ESA, "take" means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). The harvest of green turtles and their eggs is prohibited as "take" under the ESA and its implementing regulations. Specifically, the harvest of turtles is equivalent to hunting, and the harvest of eggs is collecting. Farming would require trapping, capturing, collecting, and eventually killing.

The ESA exempts from prohibition the take and import of endangered and threatened species for subsistence purposes by Alaskan Natives and non-native permanent residents of Alaskan native villages (16 U.S.C. 1539(e)); however, those provisions are specific to Alaskan Natives and permanent residents of Alaskan native villages. They provide no basis for authorizing take in any other context. The statute contains no other exceptions for cultural or subsistence take. Modifications to the statute to recognize additional exemptions are beyond our authority.

With respect to the longstanding regulatory provisions extending the section 9 prohibitions to threatened species of sea turtles, modifications to the existing protective regulations are beyond the scope of this rule. The scope of this rule is limited to the identification of green turtle DPSs and the determination of their listing statuses based on the best available scientific and commercial data. We have not undertaken to review or otherwise modify the protective regulations, which remain in effect as noted in the proposed rule.

In addition to the ESA, the Inter-American Convention for the Protection and Conservation of Sea Turtles (2001) prohibits the intentional capture, retention, or killing of, and domestic trade in, sea turtles, their eggs, parts, or products. The United States is a Contracting Party to, and is therefore bound by, the treaty and required to apply the prohibitions to all persons subject to U.S. jurisdiction. The treaty does not identify exceptions for cultural take. Currently, U.S. obligations under the treaty are not implemented through separate legislation or regulations, as sea turtles are already protected under the ESA.

Historically, the harvest of green turtles and their eggs resulted in overexploitation, one of the major factors cited in the original listings of green turtles under the ESA (43 FR 32800, July 28, 1978). Green turtle populations are vulnerable to overexploitation due to slow growth rates, late sexual maturity, and complex migratory life histories (Bjorndal *et al.*, 1999). Low levels of harvest may impede local recovery (Bell *et al.*, 2007), and positive population trends are quickly reversible (Hays, 2004; Troëng and Rankin, 2005; Broderick *et al.*, 2006; McClenachan *et al.*, 2006). For each DPS, we considered the impact of legal and/or illegal harvest of turtles and eggs.

Comment 8: We received many comments on climate change. Most commenters stated that climate change poses a threat to green turtles. Several commenters did not agree with our evaluation of climate change and its impact on green turtle DPSs. Some stated that climate change and its resulting impacts (*e.g.*, increases in temperature, sea level, ocean acidification, and the frequency and intensity of storm events) are not likely to occur. One commenter stated that climate change science and predictions have limitations and uncertainties. One commenter stated that while sea level rise is likely to result in loss of nesting habitat at insular nesting beaches, it may result in the expansion of nesting habitat at continental beaches. Some commenters stated that climate change is not likely to endanger sea turtle DPSs within the foreseeable future because turtles will adapt or change their behavior. One commenter stated that the species may not be able to adapt to climate change due to its life history, the rapidly changing shoreline, and ocean pollution. One commenter requested that the Services maintain ESA protections for all green turtle DPSs due to the increasing threat of climate change, citing the unprecedented rates of greenhouse gas emissions, increased global temperatures, accelerated sea level rise, increased extreme weather events, and the effects of other threats on green turtles (*e.g.*, fisheries bycatch and ocean pollution) magnified as a result of climate change. Two commenters stated that climate change alone, or in synergy with other factors, places DPSs in danger of extinction (*i.e.*, endangered). One commenter provided additional scientific information in support of our climate change analyses.

Response: We have reviewed the best available information on climate change, including the reports submitted with comments and many recently published peer-reviewed publications and government reports on climate change and its impacts on green turtles. While we received additional information, it is not significantly different from the information reviewed for the proposed rule and supports our evaluation of climate change impacts on green turtle DPSs in the Status Review Report and proposed rule. It does not change our proposed listing determinations. To address general comments, we provide the following summary of the best available scientific and commercial data on climate change and its impact on green turtles.

The Intergovernmental Panel on Climate Change (IPCC) was established by the United Nations Environmental Programme and World Meteorological Organization to assess climate change and its potential environmental and socio-economic impacts. The Fifth Assessment Report (IPCC, 2014) summarizes the best available scientific knowledge relevant to climate change, considering different greenhouse gas concentration pathways (*https://www.ipcc.ch/index.htm*). The IPCC Representative Concentration Pathway 8.5 is based on increasing radiative forcing through 2100. It is based on current rates of emissions continuing into the future. We use this pathway because it requires the least assumptions (*i.e.,* future rate changes) and, in the absence of data to the contrary, it is prudent to make resource management decisions based on *status quo* evidence. Though there is uncertainty as to the precise magnitude of future effects, there is very little uncertainty as to the fact that climate change is occurring and the direction of impacts from climate change. This is consistent with NMFS' recent coral listing determinations (79 FR 53852, September 10, 2014) and NMFS' recent Guidance for Treatment of Climate Change in NMFS ESA Decisions (NOAA Assistant Administrator for Fisheries Eileen Sobeck, Memorandum to NMFS Leadership Council, January 4, 2016; in revision). As described by the IPCC (2014), under Pathway 8.5:

- The global mean surface temperature is likely to increase 2.6 °C to 4.8 °C by 2100;
- Ocean acidification is likely to increase 100 to 109 percent by 2100;
- Global mean sea level will likely rise 0.45 to 0.82 m by 2100; sea level will very likely rise in at least 95 percent of the ocean area; approximately 70 percent of coastlines are projected to experience a sea level rise of within 20 percent of the global mean; and
- There is high confidence that warming, ocean acidification, and sea level rise will continue to increase for centuries beyond 2100.

Based on the above information, we do not agree with the commenters who state that climate change and its resulting impacts are not likely to occur. The IPCC provides conservative estimates of the effects of climate change. For example, its estimates of sea level rise represent the mean sea level rise that is likely to occur; under Pathway 8.5, the maximum is 0.98 m, and there is a 17 percent risk of exceeding that maximum (IPCC, 2014). In addition, studies published since the Fifth Assessment Report identify the potential for higher rates of sea level rise due to the destabilization of West Antarctic ice sheets (Joughin *et al.,* 2014; Rignot *et al.,* 2014; Trusel *et al.,* 2015) and volume or mass loss from other polar ice sheets (Helm *et al.,* 2014; Dutton *et al.,* 2015). Thus, the best available scientific and commercial data indicate that climate change is occurring and will continue to occur within the foreseeable future, likely resulting in increases in temperature, sea level rise, and ocean acidification.

Regarding the comment on limitations and uncertainties in climate change science, the IPCC uses qualitative descriptions of likelihood and confidence. In the Fifth Assessment Report, the term "high confidence" refers to the authors' judgments about the validity of findings as determined through evaluation of evidence and agreement; the term "likely" refers to a 66 to 100 percent likelihood of an outcome (IPCC, 2010). In our review of the Fifth Assessment Report, we focused on and applied outcomes and findings that were "likely" to occur and with "high confidence" findings. For example, the IPCC reports with high confidence that a large fraction of species faces increased extinction risk due to climate change during and beyond the 21st century, especially as climate change interacts with other stressors (IPCC, 2014). This conclusion is based on observational evidence that lower rates of natural climate change caused significant ecosystem shifts and species extinctions during the past millions of years, and the current changes are occurring at a faster rate over less time. The IPCC also reports with high confidence that marine organisms will face progressively lower oxygen levels and higher rates of ocean acidification and that coastal systems and low-lying areas are at risk from sea level rise (IPCC, 2014).

We agree with commenters that climate change and its impacts are a threat to green turtles. Species with high fecundity and low juvenile survival, such as sea turtles, are the most vulnerable to climate change and elevated levels of environmental variability (Cavallo *et al.,* 2015; Halley *et al.,* in review). Temperature changes and sea level rise are likely to change ocean currents and the movements of hatchlings, surface-pelagic juveniles, and adults (Hamann *et al.,* 2007; Hawkes *et al.,* 2009; Poloczanska *et al.,* 2009; Cavallo *et al.,* 2015). Though ocean acidification is likely to affect the forage-base of green turtles, including invertebrates, seagrasses, and algae, it is not clear how these changes will impact green turtles (Hamann *et al.,* 2007; Poloczanska *et al.,* 2009). Nesting beaches are likely to be impacted by climate change. Sea level rise is likely to reduce the availability and increase the erosion rates of nesting beaches, particularly on low-lying, narrow coastal and island beaches (Fish *et al.,* 2005; Baker *et al.,* 2006; Jones *et al.,* 2007; Fuentes *et al.,* 2009; Hawkes *et al.,* 2009; Anastácio *et al.,* 2014; Pike *et al.,* 2015). On undeveloped and unarmored beaches with no landward infrastructure, a typical beach profile may maintain its configuration but will be translated landward and upward (Bruun, 1962); however, along developed coastlines, and especially in areas where erosion control structures have been constructed to limit shoreline movement, sea level rise is likely to cause severe effects on nesting females and their eggs (Hawkes *et al.,* 2009; Poloczanska *et al.,* 2009). Increased storm frequency and intensity are likely to result in altered nesting beaches and decreased egg and hatchling success (Pike and Stiner, 2007; Van Houtan and Bass, 2007; Hawkes *et al.,* 2009; Fuentes *et al.,* 2011a; Dewald and Pike, 2014; Brost *et al.,* 2015). Increasing air and sea surface temperatures are strongly correlated to sand temperatures (Fuentes *et al.,* 2009; Santos *et al.,* 2015a), which could lead to embryonic mortality at 35 °C (Ackerman, 1997) and the loss of male hatchlings at 30.3 °C (Godfrey and Mrosovsky, 2006; Fuentes *et al.,* 2010b; 2011b).

Some commenters stated that sea turtles would respond to climate change via adaptation or behavioral changes. Adaptation by natural selection occurs when individuals with one heritable trait survive and reproduce (passing that trait onto their offspring) at a higher rate than individuals with other heritable traits. It occurs over many generations, and one green turtle generation is approximately 30 years (Seminoff *et al.,* 2015). As climate change progresses (*i.e.,* temperatures increase, ocean acidification increases, sea level rises, and storms increase in frequency and intensity), sea turtles that nest on low-lying beaches with inhospitable sand temperatures will produce less viable offspring than previously and as compared to those nesting at higher elevations and on beaches with sand temperatures conducive to embryonic development. This adaptation scenario will have a net effect of reducing the overall abundance of sea turtle populations in the future (*e.g.,* reduced production at the low-lying beaches and constant production at the higher elevation beaches). The capacity for green turtles to quickly adapt is questionable because they are long-lived and late maturing, and the species has previously evolved in a climate that changed at a much slower rate than projections suggest for the next 100 years (Hamann *et al.*, 2007; Hawkes *et al.*, 2009; Poloczanska *et al.*, 2009). Slow evolutionary rates (Avise *et al.*, 1992) and smaller population sizes (as a result of previous declines and relative to pre-exploitation populations; McClenachan *et al.*, 2006) may further limit the species' ability to adapt (Hawkes *et al.*, 2009). Therefore, adaptation by natural selection for green turtles is likely to be limited and may not match the rate of climate change impacts within the foreseeable future.

We agree that in response to climate change, green turtles may alter their behavior; for example, nesting females may use beaches with higher elevation or cooler sands (Santos *et al.*, 2015). However, the likelihood of altered behavior is difficult to estimate because green turtles exhibit high nesting site fidelity at some locations (Carr and Carr, 1972; Dizon and Balazs, 1982; Mortimer and Portier, 1989; Marquez, 1990; Bowen *et al.*, 1992) and low nesting site fidelity at others (Basintal 2002; Abe *et al.*, 2003). Dizon and Balazs (1982) state, "It is imperative for the well-being of the population that no alterations in the habitat be made since once imprinted the green turtle is unlikely to switch its breeding habitat." Santos *et al.* (2015a) conclude that no environmental condition may be important enough to deter a faithful nester. In addition, alternative nesting sites may not be available. Furthermore, coastal squeeze, where coastal development prevents the landward migration of beaches, may prevent the use of higher elevation areas (Fish *et al.*, 2008; Mazaris *et al.*, 2009), even on continental beaches. Alternative beaches may not provide the optimal substrate for nesting (Fuentes *et al.*, 2010a). Therefore, the best available scientific and commercial data indicates that green turtle nesting behavior alterations are not likely to ameliorate all effects of climate change on the species.

Our consideration of climate change includes efforts to limit future emissions and mitigate the impacts of climate change. After the publication of the proposed rule, 195 nations adopted the landmark Paris Agreement at the Twenty-First Conference of the Parties to the United Nations Framework Convention on Climate Change (the 2015 Paris Climate Conference, or COP 21). The Agreement will be open for signature for one year beginning on April 22, 2016, and will come into effect when ratified by 55 nations, representing 55% of global greenhouse gas emissions. Article 2.1 of the Agreement states that it "aims to strengthen the global response to the threat of climate change, in the context of sustainable development and efforts to eradicate poverty, including by . . . [h]olding the increase in the global average temperature to well below 2 °C above pre-industrial levels and to pursue efforts to limit the temperature increase to 1.5 °C above pre-industrial levels. . . ." (UNFCCC, Dec. 12, 2015, Article 2.1(a), *http://unfccc.int/resource/docs/2015/cop21/eng/l09.pdf*). Contracting parties will design their own reduction targets (their "intended nationally determined contributions"), which are to become progressively more ambitious through successive iterations over time. The parties will be required to submit plans for achieving their intended reductions and to account for their actual performance through transparent means. *See* Articles 3 and 4. Since the Paris Agreement is not yet in force, sufficient information regarding the plans of the parties for reducing emissions and the likely impact on global greenhouse gas emissions over the foreseeable future is not yet available. At this time, on the current record, we must conclude there is no basis to examine how these recent efforts may ameliorate the likely impacts of climate change in the foreseeable future. As time progresses and more information becomes available on implementation and effectiveness of the Paris Agreement, we expect that information will be incorporated into the ongoing assessments of the IPCC, which is well-recognized to be the source of the best available scientific and commercial information on climate change trends and impacts. Our future determinations under the ESA will continue to be informed by the information available from the IPCC, as well as other available climate analyses, and thus will take into account new information as appropriate.

One study assessed possible mitigation measures, which included shading or sprinkling nests with water to reduce temperatures (Jourdan and Fuentes, 2015); however, the effectiveness of such strategies to address climate change impacts has yet to be determined and is likely to be dependent on conservation resources and site-specific characteristics.

Therefore, based on the best available scientific and commercial data, we conclude that the effects of climate change present a threat to all green turtle DPSs. While this threat alone does not put any DPS in danger of extinction, climate change together with other threats places some DPSs in danger of extinction (*i.e.*, endangered) and makes others likely to become endangered within the foreseeable future (*i.e.*, threatened).

Comment 9: Several commenters stated that DPSs proposed as endangered (*i.e.*, the Central West and Central South Pacific DPSs) should be listed as threatened due to inadequate data. Several commenters stated that nesting estimates in the Central West and Central South Pacific DPSs are based on a limited number of survey locations. Some commenters, including the Guam Department of Agriculture, requested a 6-month extension for the publication of the final rule.

Response: Please see the previous section entitled, *Listing Determinations under the ESA*, which describes the listing determination process and the difference between endangered and threatened species. The ESA requires us to determine whether any species is endangered or threatened because of any one or a combination of the section 4(a)(1) factors (16 U.S.C. 1533(a)(1)) and based solely on the best available scientific and commercial data (16 U.S.C. 1533(b)(1)(A)); it does not require quantitative analyses, and it does not require us to collect new data or perform additional surveys. These requirements apply equally to endangered and threatened determinations.

Regarding the comment on the number of nesting survey locations, for each DPS we compiled the best available scientific and commercial data including peer-reviewed scientific publications, government reports, and verified unpublished data on green turtle biology and threats. The Status Review Team and two post-doctoral researchers evaluated over 600 publications on green turtles for the Status Review Report, which was peer-reviewed by 15 scientists. To further ensure that the listing determinations are based on the best available data, we requested additional information and allowed over 6 months for response (80 FR 15271, March 23, 2015). We did not receive any new information on nesting sites in the Central West or Central South Pacific DPSs. We did not receive any information that changed the listing determination for any DPS.

Regarding the request for an extension, the ESA provides that if we find that there is substantial disagreement regarding the sufficiency or accuracy of the available data relevant to the determination, we may delay the publication of the final rule for 6 months to solicit additional data (16 U.S.C. 1533 (b)(6)(B)(i)). In this instance, we do not find that there is a substantial disagreement regarding the sufficiency or accuracy of the available data on the Central West or Central South DPSs, or for any other DPS. To the contrary, we find that the best available scientific and commercial data support our proposed listing determinations, without the need for additional data. The commenters did not identify additional information that will become available and would be fundamental to our determinations. We allowed a 6-month public comment period on the proposed rule, which exceeded the 60-day minimum as outlined in our regulations (50 CFR 424.16(c)(2)). Therefore, we find there is no basis upon which to grant the request to extend the deadline for publication of the final rule.

Comment 10: The Colombian Ministry of Environment and Sustainable Development provided information on the National Programme for the Conservation of Marine and Continental Turtles in Colombia that includes education, conservation, and outreach plans; in addition, Colombia works with the Permanent Commission for the South Pacific on the Southeast Pacific Action Plan (based on the Lima Convention of 1981), which protects sea turtles and their habitats by mitigating threats through participatory strategies designed using the best available scientific and socioeconomic information. The Colombian Ministry of Environment and Sustainable Development also stated that in areas where utilization of sea turtles is deeply ingrained in the local culture, such as the La Guajira region of Colombia, changing people's attitudes about the use of sea turtles can be a long, slow process; however, these communities play a fundamental role in the conservation of sea turtles.

Response: We appreciate the comment and the efforts made to conserve green turtles. We added the information on conservation efforts in Colombia to the relevant sections of this notice on the South Atlantic and East Pacific DPSs.

Comment 11: One commenter identified several spelling mistakes, misused words, and typos.

Response: We corrected the spelling mistakes, misused words, and typos in the final rule.

Comments on the North Atlantic DPS

Comment 12: We received comments from State agencies including the Florida Fish and Wildlife Conservation Commission (FWC), the Florida Department of Environmental Protection (FDEP), the Georgia Department of Natural Resources Wildlife Resources Division, the North Carolina Wildlife Resources Commission, and the Virginia Department of Game and Inland Fisheries (VDGIF). They supported the DPS listings. The FWC and FDEP emphasized the conservation programs currently in place in Florida. The VDGIF recommended that more emphasis be placed on nesting beaches north of Florida, such as in North Carolina, as they may become more important in the future due to climate change.

Response: Regarding climate change, please see our response to *Comment 8*. We appreciate the positive response from the State agencies and their continued support on listed species conservation. We considered the best available data on green turtle demographic parameters, threats, and conservation efforts for this DPS. The estimate of total nesting abundance includes the nesting sites north of Florida (Seminoff *et al.*, 2015). Nesting beaches north of the high density nesting beaches in southeast Florida may become more important to the DPS in the foreseeable future. By listing the DPS as a threatened species under the ESA, we protect all nesting green turtles, including those that nest on beaches in North Carolina.

Comment 13: We received many comments from the public on the listing determination of the North Atlantic DPS. Several commenters supported the listing determination. One commenter supported the listing determinations and provided information on nesting abundance in Florida and an observed increase in juvenile green turtles on the reefs off Hutchinson Island, the Central Indian River Lagoon, and the Key West National Wildlife Refuge. Many commenters stated that the DPS should be listed as endangered due to the severity of threats. Several commenters stated that turtles of the Florida breeding population, originally listed as endangered, would lose protections if listed as threatened. One commenter referenced the high abundance of green turtles prior to commercial exploitation and identified the possible threat of harvest if ESA protections were removed. One commenter stated that the listing determination did not agree with the critical risk threshold in the Status Review Report, *i.e.*, that the standard for extinction was lower than the statutory definition and that the horizon for foreseeable future was beyond what could reasonably be predicted. The commenter stated that the DPS is not likely to become endangered within the foreseeable future, citing population increases, PVAs, and the critical risk threshold analysis described in the Status Review Report. This commenter requested the information used to make the listing determination.

Response: Please see the section entitled, *Listing Determinations under the ESA*, which describes the listing process, the difference between endangered and threatened species, our explanation for using a foreseeable future of 100 years, and the reasons that we did not apply the critical risk threshold, which is a higher standard (*i.e.*, requires a condition worse than the statutory definition of endangered). The best available scientific and commercial data allow us to make reasonable projections over that time frame as to the key threats that are impacting the species as well as the species' biological response (over three generations). The primary threats leading to listing are already operating on the species, so we are not relying solely on the ability to project effects into the future. Please see our response to *Comment 3* for the reasons that we did not base our determination on the PVAs. The information used to make the listing determination is provided in the Status Review Report, proposed rule, and final rule; these documents and the list of references cited in the proposed rule are available online at *http://www.nmfs.noaa.gov/pr/species/turtles/green.htm*.

We do not agree with commenters who state that the North Atlantic DPS is endangered or should not be listed under the ESA. The North Atlantic DPS is not presently in danger of extinction because of its high nesting abundance, increasing trends, connectivity, and spatial diversity, which provide some resilience against the section 4(a)(1) factors. However, the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range due to the following threats: habitat degradation, harvest of turtles and eggs, disease and predation, bycatch, channel dredging, marine debris, cold stunning, and climate change. Removing ESA protections would further increase the likelihood of endangerment. The large abundance and increasing trend of nesting females are a direct result of ESA protections and State, local, and foreign protections, which are influenced by the ESA status. If we did not list the DPS under the ESA, the important protections, financial resources, and conservation benefits associated with the ESA would not continue. Further, without listing under the ESA, it is possible that some State, local, and foreign protections would be rescinded.

Regarding the comment on turtles from the Florida breeding population, the change in status (from endangered to threatened) will not reduce protections afforded under the ESA. Threatened and endangered sea turtles receive similar protections under the ESA because longstanding protective regulations apply the prohibitions of section 9 of the statute (which automatically apply to endangered species) to threatened sea turtle species (50 CFR 17.42(b)(1); 50 CFR 223.205). As discussed in the proposed rule and in a prior response, those regulations are not affected by this listing determination rulemaking and remain in effect for threatened DPSs, such as the North Atlantic DPS. One minor change for turtles from the Florida breeding population is that, under the USFWS and FWC section 6(c)(1) agreement, any authorized employee or agent of the FWC may, when acting in the course of official duties, take or issue a conservation permit authorizing take of a green turtle for purposes consistent with the ESA and provisions of the section 6(c)(1) agreement.

Comment 14: One commenter stated, "To the extent that the Services take the position that they will not delist species unless specifically petitioned to do so, API [American Petroleum Institute] requests that the Services treat this letter as a delisting petition."

Response: The Services do not take the position "that they will not delist a species unless specifically petitioned to do so." As discussed in the proposed rule, we initiated a status review of the entire species to comprehensively identify DPSs and determine their appropriate listing status, including whether any DPSs no longer warrant listing. Thus, with or without a petition directed at any particular DPS, we used the best available scientific and commercial data (including comments submitted on the proposed rule) to make appropriate ESA listing determinations for each DPS. Stated differently, filing of such a petition at this time would not trigger consideration of new issues that are not already being thoroughly evaluated as part of the ongoing rulemaking. We considered the information presented in API's comment letter fully when making our final listing determinations. It is thus unnecessary by the commenter's own terms to consider the comment as a petition.

We find that the purported petition fails to constitute a valid petition for three additional reasons. First, were the Services to process comments on a proposed rule as petitions seeking to determine the status of the species already the subject of the proposed rule, it would create a circular and redundant process. When a petition is filed, the Services must make a 90-day finding to the maximum extent practicable, and if that initial finding is positive, it triggers a status review and ultimately a 12-month determination (50 CFR 424.14(b)(3)). If the relevant status review has already been conducted and a proposed rule to determine the status of the affected species is available for comment, there is nothing more that processing a new petition at that time could accomplish. Second, API's letter can be read as attempting to petition the Services to delist the North Atlantic DPS before the rule to list it as such has become a final agency action. To the extent that was the commenter's intent, such a preemptive petition is improper as it does not seek an action that can be presently taken. Finally, we note that our regulations require that every petition clearly identify itself as such (50 CFR 424.14(a)), a requirement not clearly met where the document is self-described as a comment letter filed within the context of an ongoing, docketed proceeding.

Comment 15: We received many comments on the section 4(a)(1) factors for the North Atlantic DPS. Though commenters generally agreed with our identification of threats, several disagreed with our analyses of these threats. One commenter provided information on the threats of climate change, fisheries bycatch, pollution, direct harvest, disease, and the inadequacy of existing regulatory mechanisms, to provide further support for our determination and the need to continue protection under the ESA without any weakening of regulations. Several commenters stated that green turtles are especially sensitive to habitat destruction at nesting sites as a result of coastal development, artificial lighting, and beach nourishment projects and in water as a result of eutrophication, pollution, and harmful algal blooms. One commenter stated that poaching is a major threat in the North Atlantic DPS. Several commenters stated that the DPS should be considered endangered as a result of the high incidence of FP in green turtles found in Florida and the spread of the disease geographically (from central and southern Florida to northeast and northwest Florida) and in incidence. One commenter stated that "from 1980–2005, 22.2 percent of stranded green sea turtles were afflicted; last year, 28.7 percent of all green sea turtles were afflicted." Several commenters stressed the importance of increasing threats, such as FP, climate change, marine debris, bycatch, and boat strikes. Several commenters stated that climate change should be considered a significant threat for the North Atlantic DPS, and the listing status for Florida green turtles should remain as endangered based on this threat. One commenter stated that green turtles are especially sensitive to sea level rise, because they prefer to nest on narrower, steeper, and eroded beaches. They stated that the combination of coastal development and sea level rise could be devastating to the DPS; however, the removal of structures such as seawalls and buildings might mitigate such effects. One commenter stated that the long-term effects of the *Deepwater Horizon* oil spill (Mississippi Canyon 252) remain to be seen. One commenter stated that the North Atlantic DPS is not exposed to any threats that warrant its listing as threatened under the ESA. The commenter stated that the amount of coastal armoring permits in Florida has decreased between 2001 and 2005, protection has increased in other countries, artificial lighting is controlled by local lighting ordinances, and sea level rise is not considered an imminent threat. The commenter stated that impacts from armoring are offset by beach nourishment programs that place sand on eroding beaches, increasing green turtle nesting habitat.

Response: For our general responses regarding the section 4(a)(1) factors, please see *Comments 6, 7,* and *8.* We list the North Atlantic DPS as threatened because of habitat destruction and modification, the harvest of turtles and eggs, disease and predation, inadequate regulatory mechanisms, bycatch, channel dredging, marine debris, cold stunning, and climate change. Based on our review of the best available scientific and commercial data, the DPS is not presently in danger of extinction due to a single factor (*e.g.,* FP or climate change) or the section 4(a)(1) factors cumulatively, when considered in the context of the demographic parameters (*i.e.,* high abundance, increasing trends, and spatial diversity), which provide resilience to the DPS at present. While a species may be listed based on any one of the five factors, in many instances, more than one factor may cause the species to meet the definition of a threatened or endangered species. Alternatively, while each individual factor may not cause the species to meet the definition of threatened or endangered, the cumulative effect of multiple factors may cause the species to be listed.

Regarding the comments on FP, the disease results in internal and/or external tumors that may grow large enough to hamper swimming, vision, feeding, and potential escape from predators. We acknowledge the increasing distribution and incidence of FP, particularly in Florida. The threat is likely to increase, given the continuing, and possibly increasing, human impacts to, and eutrophication of, coastal marine ecosystems that may promote this disease (NMFS, in progress). However, FP is not always lethal, and photographic evidence from Florida shows that the tumors on some green turtles go into regression (Hirama, 2001; Hirama and Ehrhart, 2007; NMFS, in progress).

Regarding the comments on habitat destruction and protection, we considered habitat modification and destruction impacts to the extent they are known and based on the best available data, including qualitative information (*i.e.,* the ESA does not require quantitative data, which in this case are limited). There has been an increase in coastal armoring structures permitted by the FDEP over the last 5 years particularly on Singer Island in Palm Beach County, a high density nesting beach. In many areas, residential and commercial properties, as well as breakwaters, jetties, seawalls, and other erosion control structures designed to protect public and private property, continue to be permitted and built. Such coastal development places increasing pressure on beach systems and negatively affects nesting habitat. While mitigation measures (*e.g.,* lighting ordinances and construction setbacks) provide important protections, they do not remove the threats or reduce them to insignificant levels. Beach nourishment programs can provide nesting habitat where it had been previously destroyed or offset impacts from other coastal measures; however, they also alter sand characteristics and nearshore foraging habitat. At best, such programs help to reduce impacts but do not provide new benefits to the turtles.

Regarding the comment on poaching, as explained in more detail in the Status Review Report, the harvest of turtles and eggs remains legal in several countries within the range of the North Atlantic DPS. Turtles are legally and illegally harvested in foraging areas. Eggs are harvested at many nesting beaches.

Regarding the comment on the *Deepwater Horizon* oil spill, we agree that the long-term effects remain to be seen because the spill was particularly harmful to post-hatchlings and surface-pelagic juveniles (Witherington *et al.,* 2012) by temporarily destroying their *Sargassum* habitat (Powers *et al.,* 2013) and resulting in the ingestion of contaminants.

Numerous other natural and manmade factors affect the continued existence of this DPS. Regulatory mechanisms contained within international instruments are inconsistent and likely to be insufficient. While some regulatory mechanisms should address direct and incidental take for this DPS, it is unclear to what extent such measures are implemented and effective. The species is conservation-dependent and positive population trends are likely to be curtailed or reversed without alternate mechanisms in place to continue existing conservation efforts and protections afforded under the ESA. We conclude that the North Atlantic DPS is threatened by the above section 4(a)(1) factors.

Comment 16: Several commenters supported an endangered listing determination for the North Atlantic DPS, citing the criteria in the Recovery Plan for the U.S. Population of Atlantic Green Turtle (NMFS and USFWS, 1991); however, one commenter cited the criteria in the Recovery Plan as a basis for delisting the North Atlantic DPS.

Response: The ESA requires us to determine whether a species is threatened or endangered because of the 4(a)(1) factors, based solely on the best available data after considering conservation efforts. Section 4(f)(1) requires us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless the Secretary finds that such a plan will not promote the conservation of the species (16 U.S.C. 1533(f)(1)). The information included in such plans informs but does not dictate listing determinations. *See Friends of Blackwater* v. *Salazar,* 691 F.3d 428 (D.C. Cir. 2012).

The 1991 Recovery Plan was written prior to the identification of the DPS and only applies to the U.S. population of the Atlantic green turtle (whereas the North Atlantic DPS includes foreign populations and does not include turtles nesting in the U.S. Virgin Islands). The 1991 Recovery Plan identifies recovery criteria (NMFS and USFWS, 1991); however, these criteria apply to delisting, not to changes in listing status (*i.e.,* from endangered to threatened). Some, but not all, of the recovery criteria for this population have been met. Nesting in Florida averages over 14,000 nests annually for the last 6 years (*http://myfwc.com/media/2988445/greenturtlenestingdata10–14.pdf;* FWC, pers. comm., 2015); however, less than 25 percent of all available nesting beaches and less than 50 percent of nesting activity are in public ownership. Similarly, the species' status in nearshore and inshore waters and reduction in stage class mortality have not been evaluated.

To make our listing determination, we evaluated the section 4(a)(1) factors in the context of the demographic parameters for this DPS (*i.e.,* we did not directly evaluate whether the U.S. Atlantic population has met the recovery criteria). Based on the best available scientific and commercial data, we conclude that the North Atlantic DPS is not presently in danger of extinction but is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (*i.e.,* threatened under the ESA) because of habitat destruction and modification, the harvest of turtles and eggs, disease and predation, inadequate regulatory mechanisms, bycatch, channel dredging, marine debris, cold stunning, and climate change.

Comments on the Mediterranean DPS

Comment 17: One commenter requested a discussion of the threat from wars in Syria and Libya.

Response: Green turtles nest on Syrian beaches and forage in the waters off Libya; there is a migratory corridor between these nesting and foraging hotspots (Stokes *et al.,* 2015). Stokes *et al.* (2015) tracked 34 turtles from Cyprus, Turkey, Israel, and Syria; over half of the turtles migrated to the Gulf of Sirte and the Gulf of Bomba in Libya. The Gulf of Bomba and nearby Ain Gazala have been identified as potential marine protected areas (Badalamenti *et al.,* 2011); the authors also recommend the Gulf of Sirte for consideration as a marine protected area (Stokes *et al.,* 2015). As summarized by Stokes *et al.* (2015), much of Libya's coastline is not degraded and is relatively unpopulated; total fisheries catch is an order of magnitude lower than that of neighboring Egypt and Tunisia. Marine exploitation has increased, however, and conservation efforts have been delayed by political unrest (Badalamenti *et al.,* 2011). Geopolitical instability further complicates conservation efforts (Katsanevakis *et al.,* 2015). In an interview on the Stokes *et al.* (2015) findings, B.J. Godley indicated that political instability can have positive (by slowing exploitation and development and creating de-facto wildlife refuges) and negative (by delaying the identification of marine protected areas) effects on conservation (Gertz, 2015; *http://www.takepart.com/*

article/2015/02/14/endangered-green-turtle-mediterranean-libya). Because of the possibility of positive and negative effects, and without specific information on the likely impacts on green turtles, we cannot determine how such conflicts are likely to impact the Mediterranean DPS. In any case, we proposed to list this DPS as an endangered species, and such information would not change our listing determination.

Comments on the South Atlantic DPS

Comment 18: One commenter suggested combining the North and South Atlantic DPSs; however, another commenter stated that the separation of the North and South Atlantic DPSs is supported by recent studies (Putman and Naro-Maciel, 2013; Naro-Maciel *et al.*, 2014b). The United Kingdom (UK) Department for Environment, Food, and Rural Affairs supported the threatened status of the South Atlantic DPS but provided the following information about the Ascension Island nesting site: The best available data on the Ascension Island population is provided by Weber *et al.* (2014); the average size of nesting females declined from a mean carapace length of 116.0 cm in 1973–1974 to 111.5 cm in 2012 (Weber *et al.*, 2014); and predation by feral dogs and especially cats, which were eradicated in 2004, is no longer a significant source of mortality for hatchlings. One commenter stated that fewer than 10 green turtles nest on monitored index beaches annually in Dominica and that these numbers are lower than a generation ago due to poaching of turtles and eggs. One commenter suggested renaming the South Atlantic DPS because its boundary occurs north of the equator.

Response: We appreciate the comments from the UK Department for Environment, Food, and Rural Affairs and their efforts to conserve green turtles. We reviewed and evaluated the information on turtles at Ascension Island and Dominica and determined that it does not change the proposed listing determination for the South Atlantic DPS.

Regarding the suggestion to combine the North and South Atlantic DPSs, the best available scientific and commercial data support the identification of the North and South Atlantic DPSs. Genetic, tagging, tracking, and modeling studies support the discreteness of the North and South Atlantic DPSs (Baudouin *et al.*, 2015; Seminoff *et al.*, 2015). In addition to the information provided in the Status Review Report, nuclear (microsatellite) and mtDNA analyses reveal a strong, ancient barrier to dispersal between northern and southern Atlantic green turtles (Naro-Maciel *et al.*, 2014b), as divided by our definition of the North and South Atlantic DPSs (*i.e.*, the equator lies south of and does not coincide with the genetic barrier). The breeding seasons of the DPSs are temporally distinct, potentially limiting mixing during reproductive migrations (Naro-Maciel *et al.*, 2014b). Ocean circulation models (*i.e.*, a potential proxy of juvenile turtles, though see Putman and Mansfield, 2015) indicate that the majority of particles arising from the northern or southern Atlantic are likely to remain within the northern or southern Atlantic, respectively (Putman and Naro-Maciel, 2013).

Regarding the suggestion to rename the South Atlantic DPS, the vast majority of the range of the South Atlantic DPS lies in the South Atlantic Ocean. We find that the nomenclature appropriately distinguishes this DPS from the North Atlantic DPS and is consistent with the terminology used to name all DPSs.

Comments on the Southwest Indian DPS

Comment 19: The UK Department for Environment, Food, and Rural Affairs provided additional information on the British Indian Ocean Territory (BIOT), which occurs within the range of the Southwest Indian DPS, stating that: (1) Available information on nesting turtles within the BIOT includes "only fairly crude assessments of population size and seasonality," while satellite data indicate movement throughout the Indian Ocean; and (2) it is highly unlikely that, given its isolation, the BIOT nesting population would be supplemented by immigrants from elsewhere. The Department for Environment, Food, and Rural Affairs recommends waiting for additional census data before considering whether to downgrade the conservation status of these sea turtles. The Embassy of the Republic of Mauritius agreed with the proposed listing.

Response: We appreciate the comments from the UK Department for Environment, Food, and Rural Affairs and the Embassy of the Republic of Mauritius and their efforts to conserve green turtles. The status for this DPS has not been changed; we listed the species as threatened in 1976 and now list the Southwest Indian DPS as threatened under the ESA. The ESA requires us to base our listing determinations on the best scientific and commercial data available, after conducting a review of the status of the species and considering conservation efforts (16 U.S.C. 1533(b)(1)(A)). Because we have sufficient data to determine the listing status of this DPS and did not receive additional data during the 6-month comment period on the proposed rule, there is no basis to delay our determination while additional census data are collected.

The Status Review Team considered the BIOT, which includes the seven atolls of the Chagos Archipelago, where sea turtle nesting is common (Mortimer and Day, 1999). The estimated total nester abundance of 1,800 nesting females (Seminoff *et al.*, 2015) was based on the Mortimer and Day (1999) estimate of 400 to 800 females nesting annually at the Chagos Archipelago, which we consider to be the best available scientific and commercial data. Mortimer and Day (1999) state that green turtles and their habitat are well protected by the BIOT administration; however, monitoring and conservation efforts are not sufficient to adequately reduce all threats.

Comments on the East Indian-West Pacific DPS

Comment 20: The Forestry Bureau of the Taipei Economic and Cultural Representative Office agrees with the listing under the ESA.

Response: We appreciate the comment from the Forestry Bureau of the Taipei Economic and Cultural Representative Office and their efforts to conserve green turtles.

Comments on the Central West Pacific DPS

Comment 21: We received several comments on the section 4(a)(1) factors for the Central West Pacific DPS. One commenter stated that human populations in Guam, CNMI, and the Federated States of Micronesia are decreasing. One commenter stated that development is not a threat. Several commenters stated that poaching of nesting turtles is a problem in the Central West Pacific DPS; one commenter stated that allowing cultural take would resolve this issue, though another disagreed. One commenter stated that bycatch is a threat in CNMI. One commenter stated that 4,000 years ago, sea level was 1.8 m higher than it is today in CNMI (Amesbury, 2007), and one commenter stated that sea level rise is not a threat.

Response: Regarding cultural take, please see our response to *Comment 7*. The harvest of sea turtles or their eggs is illegal under the ESA and its regulations, the Inter-American Convention for the Protection and Conservation of Sea Turtles, and local laws in CNMI (CNMI Public Law 02–51 1981) and Guam (Endangered Species Act of Guam, 1979). Despite these protections, poaching occurs in CNMI (CNMI–DLNR 2006–2009, 2011, 2013; Summers *et al.*, in progress) and Guam (*http://www.noaanews.noaa.gov/stories2008/20080729_seaturtle.html; http://dawr.guam.gov/wildlife/sea-turtles/*). The best available data indicate that past poaching and harvest have led to the low nesting abundance of the Central West Pacific DPS, whereas the protection of turtles and their habitat has led to recent increases in foraging turtles (Martin *et al.*, 2016). Based on the demographic parameters of the DPS, including its low nesting abundance, we conclude that it has little resilience against threats, especially those that remove turtles from the population, such as poaching and the harvest of turtles and eggs. Bycatch in subsistence and small-scale commercial fishing operations is also a concern.

Regarding the comments on development and human population size, threats to nesting beaches include construction (and associated lighting), military activities, public use of beaches, and beach driving (NMFS and USFWS, 1998; CNMI Coastal Resources Management Office, 2011; Palacios, 2012; Wusstig, 2012). Coastal erosion has been identified as a high risk in the CNMI due to the existence of concentrated human population centers near erosion-prone zones; it is likely to be exacerbated by sea level rise (CNMI Coastal Resources Management Office, 2011). In Guam, turtle densities are highest where there are healthy coral reefs and seagrass beds, low human densities, and marine protected areas (Martin *et al.*, 2016). Though human population density is correlated with turtle density, our major concern is with coastal development and the resulting degradation of nesting beaches and foraging areas. Human populations in Guam, CNMI, and the Federated States of Micronesia have increased since the listing of the green turtle in 1976. Since 2000, human populations have increased in Guam and decreased in CNMI and the Federated States of Micronesia (World Bank, 2015; *https://www.census.gov/newsroom/releases/archives/2010_census/cb11-cn179.html*).

Regarding the comments on sea level rise, sea level changes have occurred throughout the history of the species (*e.g.*, Grant *et al.*, 2012), but rarely at the rate likely to occur as a result of anthropogenic climate change (IPCC, 2014). Furthermore, sea level rise did not occur in the presence of other threats, such as unprecedented ocean acidification (Honisch *et al.*, 2012), overexploitation, fisheries bycatch, and habitat degradation due to coastal development, pollution, and other anthropogenic causes. Additionally, the effects of sea level rise are likely to be exacerbated by the increased frequency and intensity of storm events (IPCC, 2014). As described by Summers *et al.* (in progress), water inundation and accompanying erosion from tropical storms, typhoons, and storm water drainage impacted 7.5 percent of inventoried Saipan nests ($N = 160$) between 2007 and 2013. We expect increases in the rate of such impacts within the foreseeable future.

We conclude that the Central West Pacific DPS is endangered by a combination of section 4(a)(1) factors.

Comment 22: We received several comments on the listing determination for the Central West Pacific DPS. Senator Palacios (CNMI) stated that though NMFS supports a contractor to perform research on green turtles in CNMI, resources for data collection are insufficient. Some commenters stated that data are limited and lacking quantitative analyses and that they often observe in-water sea turtles (though another commenter never sees sea turtles). The Guam Department of Agriculture suggests listing the DPS as threatened due to data limitations (including limited survey effort) and naturally low abundances; the Guam Department of Agriculture also requests information on whether nations within the range of the Central West Pacific DPS were contacted, how the endangered listing would solidify protection of the species, and whether the recovery plan will be updated. The CNMI Department of Lands and Natural Resources provided comments on the many in-water turtles around Tinian, suggested the possibility of nesting in the northern islands, and disagreed with the endangered listing status because it might increase the extinction risk and hinder recovery (though another commenter did not agree with this assessment and did not understand how the harvest of turtles for cultural reasons would result in conservation) and further reduce the possibility of cultural harvest.

Response: Please see our responses to *Comment 3* (regarding turtle observations), *Comment 7* (regarding cultural harvest), and *Comment 9* (regarding perceived data limitations).

Regarding the comments on data, to make our proposed listing determination, we evaluated the best available scientific and commercial data, which included information from several surveys (NMFS and USFWS, 1998; Bureau of Marine Resources, 2005; Barr, 2006; Palau Bureau of Marine Resources, 2008; Trevor, 2009; Maison *et al.*, 2010; H. Suganuma, Everlasting Nature of Asia, pers. comm., 2012; J. Cruce, Ocean Society, pers. comm., 2013). For our final listing determination, we also reviewed additional surveys, which did not provide significant new information or change our listing determination (Kolinski *et al.*, 2001; Kolinski *et al.*, 2004; Kolinski *et al.*, 2005; Kolinski *et al.*, 2006; Jones and Van Houtan, 2014; Martin *et al.*, 2016; Summers *et al.*, in progress). We conclude that data on nesting turtles (rather than foraging turtles, as discussed in comments and at public hearings) provide the best available scientific and commercial data for assessing resilience.

Regarding the suggestion to list the DPS as threatened, based on the best available scientific and commercial data, we find the species to be in danger of extinction throughout all or a portion of its range as a result of the present and threatened modification of its habitat, poaching of turtles and eggs, disease and predation, fisheries bycatch, marine debris, and climate change. Regulatory mechanisms and conservation efforts are inadequate to remove the impact of these threats, and the DPS has little resilience to such threats due to its low nesting abundance and limited nesting site diversity.

Regarding the comment on naturally low abundance and the possibility of additional nesting sites, the low nesting abundance is likely a result of previous and continued harvest of turtles and eggs (Groombridge and Luxmoore, 1989). We are not aware of any additional nesting data for the northern islands and did not receive any information on additional nesting sites during the 6-month public comment period.

Regarding the information requests and concerns over the endangered status, upon publication of the proposed rule, we notified other nations and requested their comments. We intend to update the recovery plans in the future after the DPS listings are finalized; however, we do not have an anticipated completion date for such plans at this time. The updated listings will allow for more specialized protection of each DPS. The endangered status of the Central West Pacific DPS will highlight it as a conservation priority among green turtle DPSs. We do not agree that the endangered status will increase the extinction risk and hinder recovery. Past ESA protections have led to improving trends in the Central West Pacific (Martin *et al.*, 2016), and we expect such improvements to continue.

Comments on the Central South Pacific DPS

Comment 23: We received several comments on the listing determination for the Central South Pacific DPS. The Governor of American Samoa stated that the endangered status would impact fisheries, fishing grounds, and the economy without providing the DPS with additional protection (*i.e.,* relative to the current threatened status). In addition to these concerns, the Department of Marine and Wildlife Resources of American Samoa stated that the Status Review Report and proposed rule do not provide rigorous scientific assessment of threats of the Central South Pacific DPS because a PVA was not performed, there was limited survey effort in the Central South Pacific, the estimate of nesting female abundance was not weighted to potential available habitats, and the recorded decline was based on one nesting site in French Polynesia. Others provided similar comments and requested further study of the DPS. One commenter stated that the nesting estimate should be weighted for survey effort. One commenter questioned whether turtles from American Samoa and French Polynesia should be part of the same DPS.

Response: Please see our responses to *Comment 3* and *Comment 9* regarding the process and data used to make listing determinations and the difference between threatened and endangered species. The ESA does not allow consideration of economic issues for listing determinations.

Regarding the comment on the impacts of the change in status, the new listings will allow for more specialized protection of each DPS. The endangered status of the Central South Pacific DPS will highlight it as a conservation priority among green turtle DPSs. This may encourage conservation actions in other nations. The status change for turtles in American Samoa is unlikely to result in additional implementation burdens because of longstanding regulations protecting threatened species in a manner similar to endangered species (50 CFR 17.42(b)(1); 50 CFR 223.205).

Regarding the comments on surveys and assessments, for the Central South Pacific DPS, the best available scientific and commercial data are summarized in the Status Review Report and include, but are not limited to, unpublished nesting and in-water surveys data in American Samoa collected by NMFS and the Department of Marine and Wildlife Resources of American Samoa. In the proposed rule, we requested all data on nesting locations, abundance, trends, and threats, to ensure the identification and application of the best available data; however, we did not receive additional information for this DPS. We conclude that the data identified in the Status Review Report and applied in the proposed and final rule represent the best available scientific and commercial data and are sufficient to make a listing determination on the Central South Pacific DPS.

Regarding the comments on weighting data, to determine the status of the DPS, we analyzed the best available data on the section 4(a)(1) factors in the context of demographic parameters, including nesting abundance and trends. Nesting abundance was not weighted to potential available habitat or survey efforts because such data are not available. Instead, the Status Review Team provides two estimates of total abundance of nesting females. The first estimate of approximately 2,900 nesting females was based on 37 quantified nesting sites (Seminoff *et al.,* 2015). The Status Review Team provided a second estimate (approximately 3,600 nesting females) based on an additional 700 nesting females at 22 unquantified nesting sites, for which only qualitative information was available (Seminoff *et al.,* 2015). Such levels of abundance do not provide resilience against threats that remove green turtles from the population, such as harvest and stochastic events, which increase the extinction risk for small populations (Schaffer, 1981; Wright and Hubbell, 1983; Lande *et al.,* 2003). There appears to be a declining trend at the largest nesting beach in French Polynesia, which is considerably larger in abundance than all other known nesting beaches (Seminoff *et al.,* 2015). In addition, previous reports on nesting abundance in American Samoa indicate significant declines relative to historical levels (Tuato'o-Bartley *et al.,* 1993; Craig *et al.,* 2004). Though we considered increasing nesting trends at smaller nesting beaches (Seminoff *et al.,* 2015), we conclude that such trends provide little resilience to the DPS, which is endangered by habitat destruction and modification, overexploitation, predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, and climate change.

Regarding the comments on the composition of the DPS, turtles nesting in American Samoa and French Polynesia commonly exhibit haplotypes from Clade III, which are uncommon in other DPSs; satellite tagging data indicate that these turtles share foraging habitat in Fiji, French Polynesia, and American Samoa (Seminoff *et al.,* 2015; NMFS, unpublished data, 2015). Therefore, we include turtles nesting and foraging in American Samoa and French Polynesia in the Central South Pacific DPS.

Comment 24: One commenter reported reef damage as a result of the recent tsunami in American Samoa and requested a discussion of the impacts.

Response: Tsunamis can destroy or modify nesting beach and marine habitats for green turtles. They deposit marine debris, which can entangle or be ingested by foraging turtles, on reefs. After the tsunami of September 29, 2009, over 8,000 pounds of debris were removed from 74 km of coral reef habitat in American Samoa (*http://coralreef.noaa.gov/aboutcrcp/news/featuredstories/dec09/asdebris/welcome.html*). The frequency and intensity of storms are likely to increase as a result of climate change (IPCC, 2014) and are considered an increasing threat to the DPS. We considered these threats in our analysis of the Central South Pacific DPS, which we list as endangered.

Comments on the Central North Pacific DPS

Comment 25: We received many comments on the listing determination for the Central North Pacific DPS. Most commenters agreed with our listing determination, stating that the DPS should be listed under the ESA because it still faces numerous threats. One commenter stated that the Services cannot rely on politics or personal observation but must list the DPS as threatened (and cannot delist it) to comply with ESA, which requires us to base our listing determinations on the best available scientific and commercial data. Some commenters stated that the DPS should be listed as endangered because of the numerous threats and small nesting population abundance. Several commenters stated that the DPS should be delisted because of increasing nesting trends, observations of increasing in-water sea turtle abundance, or to reward conservation efforts and encourage similar efforts throughout the Pacific Islands. Several commenters questioned why the PVA and critical risk threshold were not used to determine the status of the DPS. Two commenters requested that NMFS perform in-water surveys to assess abundance prior to making a determination. The State of Hawai'i Department of Land and Natural Resources (Hawai'i DLNR) expressed support for the conservation efforts of the Services in partnership with Hawai'i DLNR, nonprofit organizations, and communities, and stated that their Marine Wildlife Program, funded by NMFS' Species Recovery Grants to States, has distributed over 200,000 barbless circle hooks to the fishing community.

Response: Please see our responses to *Comment 3* (regarding the listing determination process, rewarding conservation efforts, PVAs, and critical risk thresholds), *Comment 4* (regarding turtle observations), and *Comment 9* (regarding perceived data limitations and requests for additional surveys).

We considered the increasing nesting trend, along with the small nesting population size and limited spatial structure, during our evaluation of the demographic factors. We concluded that these demographic parameters do not demonstrate adequate resilience against the threats of habitat loss and modification, disease and predation, inadequate regulatory mechanisms, bycatch, marine debris, boating activities, climate change, and limited nesting site diversity (*i.e.,* 96 percent of nesting occurs at one low-lying atoll). For these reasons, we must list the DPS under the ESA. We do not list the DPS as endangered because of the positive nesting trend, conservation efforts, and the success of ESA protections in reducing the impact of some threats (especially the harvest of turtles and eggs). We list the DPS as threatened because it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range because of the section 4(a)(1) factors, listed above. We made this determination solely on the basis of the best available scientific and commercial data (identified in the proposed rule and Status Review Report) and after taking into account the conservation efforts of the State of Hawai'i, which include a variety of effective outreach and education programs, including the distribution of barbless circle hooks to reduce hook and line bycatch of turtles.

Comment 26: We received many comments on the section 4(a)(1) factors for the Central North Pacific DPS. Many commenters identified threats to the Central North Pacific DPS, including entanglement in and ingestion of marine debris, accidental take in fisheries, FP, climate change, coastal development and beach use in the main Hawaiian Islands (MHI), and harvest of turtles and eggs. One commenter identified an increase in nesting turtles at Turtle Bay on Oahu but stated that nests are destroyed by high surf, beach driving, and beach usage (including using a nest as a fire pit) and that turtles are threatened by poaching, harassment, pollution, and bycatch. One commenter requested a discussion of the impacts on the DPS caused by pollution around Johnston Atoll, vessel groundings in the Northwestern Hawaiian Islands (NWHI), natural disasters, and random variation and stochasticities. One commenter requested a discussion of how impacts to individuals affect the DPS (*e.g.,* how the loss of Whale-Skate Island impacted the DPS). One commenter stated that there is little that can be done to protect known nesting beaches from the public, unless all development activities come to a halt and are reversed. One commenter described an increase in turtles at the Honokohau Harbor since poaching ended about a decade ago. One commenter stated that hatchlings at Moomomi have no significant predators. Several commenters stated that FP is not a threat to the DPS. One commenter stated that Hawai'i-based longline fisheries are not a threat to green turtles of any DPS and that the new listing should not result in the reinitiation of ESA section 7 consultations. Hawai'i DLNR identified several threats to nesting habitat including, in the NWHI, the inundation of nests due to sea level rise and in the MHI, coastal development, vehicular and pedestrian traffic, beach pollution and modification, and erosion. They also identified fishing and FP as threats. Regarding inadequate regulatory mechanisms, Hawai'i DLNR stated a need to increase coordination and data sharing; they stated their intention to compare existing State regulations to Federal regulations to identify needs or gaps and to work with NOAA fisheries to develop a State management plan. Hawai'i DLNR provided information on laws regulating the use of gill nets that have reduced bycatch by requiring inspection every 2 hours and removal after 4 hours; lay nets (a type of gill net) must be registered and tagged, and usage is restricted to one at a time, only during daylight hours, and in depths of less than 25 feet (for non-commercial users).

Response: Please see our responses to *Comments 6* and *8* for general information on the section 4(a)(1) factors and the impacts of climate change. We appreciate the State of Hawai'i DLNR's comments and continued efforts to conserve green turtles. As indicated by the State of Hawai'i DLNR and other commenters, the Central North Pacific DPS is threatened by the following 4(a)(1) factors, described in detail in the Status Review Report and proposed rule: Present and threatened habitat loss and degradation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, vessel activities, limited spatial diversity, and climate change. We do not have adequate data on poaching to assess the impact of this threat on the DPS.

Regarding the comment on the destruction or modification of habitat at Johnston Atoll, previous military activities, including nuclear testing and chemical weapons incineration, polluted the beaches and surrounding marine ecosystem (*http://www.fws.gov/refuges/profiles/index.cfm?id=12515*). Balazs (1985) described the potential impacts, which include petroleum contamination that adversely affects turtles by external fouling, ingestion, and interference with olfactory perception and food supply (Coston-Clements and Hoss, 1983). Underwater explosions of previously unexploded ordnances destroy turtle foraging habitats (Balazs, 1985). Radioactive particles were spread over a portion of Johnston Atoll and nearshore waters and potentially concentrated in algae eaten by turtles (Balazs, 1985). Additional discharges include heavy metals, nerve gas, chemical weapons, herbicides, organophosphorus compounds, and the unknown contents of discarded 55 gallon drums, which have the potential to directly impact turtles and contaminate the turtles' forage base (Balazs, 1985).

Regarding the comment on destruction or modification of habitat by vessel groundings, such incidents damage foraging habitat and reef-associated organisms (*i.e.,* green turtles' prey base) and release contaminants (*e.g.,* fuel, hazardous substances, etc.), which threaten foraging habitat and prey (Keller *et al.,* 2009). Such groundings are possible wherever ships navigate through shallow waters (*i.e.,* nearshore areas throughout the Hawaiian Archipelago). Thirteen reported vessel groundings have occurred in the NWHI in the last 60 years (Keller *et al.,* 2009); recent groundings in the MHI include the 2005 *M/V Cape Flattery* and 2009 *USS Port Royal* incidents. It is impossible to predict the number or severity of future vessel groundings; however, given the data on previous groundings, it is reasonable to expect additional groundings near green turtle foraging habitat, which occurs throughout the Hawaiian Archipelago. Like past events, these groundings are expected to modify foraging habitat and reduce the amount of available prey in the area.

Regarding the comment on loss of habitat at Whale-Skate Island, the disappearance of Whale-Skate Island at French Frigate Shoals (FFS) was due to erosion from severe winter storms in 1998 and 1999 (Antonelis *et al.*, 2006; Lowry *et al.*, 2011). We do not know how the disappearance of Whale-Skate Island impacted the population because regular surveys had not been performed on that island. Turtles may have nested at neighboring islets of FFS; however, some may not have nested or may have nested in suboptimal habitats. Survey data indicate that the disappearance of Whale-Skate Island did not result in unusual increases in nesting at East Island in 1998, 1999, or 2000 relative to prior years (Humburg and Balazs, 2014). Furthermore, radio telemetry of four nesting females and four females at Trig and Whale-Skate Islands demonstrated that the turtles remained near these islands and did not travel the 9 km to East Island within a nesting season; over multiple years, only 33 percent of males and 24 percent of females strayed from Trig and Whale-Skate Islands (Dizon and Balazs, 1982). The authors concluded that once imprinted on a nesting beach, a green turtle is unlikely to switch its breeding habitat (Dizon and Balazs, 1982). Dizon and Balazs (1982) also emphasized the importance of maintaining foraging habitats and nesting beaches as free from disturbing influences as possible. Coastal development may result in the loss or modification of nesting and basking beaches and the nearshore habitats necessary for the reproductive success of the DPS.

Regarding the comment that little can be done to protect nesting beaches without halting or reversing all development, our listing determination is based on whether the species meets the definition of threatened or endangered, not whether activities could be performed. Nevertheless, we note that less drastic measures (such as minimizing impacts of artificial lighting, construction, vehicular and pedestrian traffic, and pollution on beaches during nesting seasons) are effective for protecting nesting beaches.

Regarding the comments on predation, introduced species, such as mongoose, rats, dogs, feral pigs, and cats, prey on eggs and hatchlings at some nesting beaches in the MHI. Although hatchlings at Moomomi may have no significant land predators, they are likely to encounter predators at sea, including sea birds, sharks, and other large fish.

Regarding the comments on FP, we agree with the commenters who identified FP as a threat to the DPS. In a study of 3,732 green turtle strandings in Hawai'i between 1982 and 2003, FP was the most common cause of stranding (28 percent) and had a specific mortality rate of 88 percent (Chaloupka *et al.*, 2008).

Regarding the comments on bycatch and the inadequacy of existing regulatory mechanisms, after FP, fishing line and gillnet entanglement are the leading cause of stranding and mortality of green turtles in Hawai'i (Work *et al.*, 2015). The State of Hawai'i has enacted important laws for gill and lay net fisheries. Requiring inspection of nets every 2 hours reduces, but does not eliminate, bycatch risk; entanglement and drowning still occur and are likely underreported (NMFS, 2012; Francke, 2013). As stated in the proposed rule, measures employed by U.S. longline fisheries have reduced green turtle interactions to negligible levels; however, reinitiation of consultation is still required if a new species is listed and may be affected by a Federally permitted action (50 CFR 402.16(d)).

Regarding the comment on natural disasters, since 1950, more than 50 hurricanes, tropical storms, and tropical depressions have affected Hawai'i. We expect climate change to increase the frequency and intensity of such events (IPCC, 2014). Storm events during the nesting season are likely to disrupt green turtle nesting activity and hatchling production by flooding or exposing nests and altering thermal conditions (Van Houtan and Bass, 2007), resulting in reduced cohort abundance. These events can also degrade turtle nesting habitat by reducing or eliminating sandy beaches and creating barriers to adult and hatchling movements. A single event is unlikely to result in large-scale losses over multiple nesting seasons; however, the increased frequency of such events combined with the effects of sea level rise increase the likelihood of this scenario (Baker *et al.*, 2006; Keller *et al.*, 2009; Reynolds *et al.*, 2012).

Regarding the comment on stochasticities, irregular, random, and stochastic events, such as those described above, increase the extinction risk of small populations (Schaffer, 1981; Wright and Hubbell, 1983; Lande *et al.*, 2003). Stochastic perturbations (such as demographic, environmental, and genetic stochasticities and natural catastrophes) may result in extinction even in an environment that, on average, is favorable for growth and persistence (Schaffer, 1981). Therefore, we are especially concerned about the effects of such threats on the Central North Pacific DPS.

Comment 27: We received many comments regarding the impact of climate change on the Central North Pacific DPS. One commenter did not think that climate change would affect nesting at FFS because the turtles would find alternative nesting sites and because nesting across the season and years provides resilience against storm events. One commenter asked how coastal development and climate change together would affect the DPS. Hawai'i DLNR requested additional information regarding the projected timeframe when FFS might be inundated and the nesting sites unavailable.

Response: Please see our responses to *Comments 8* (regarding climate change) and *24* (responses to nesting habitat loss). The following information on climate change is specific to the Central North Pacific DPS.

Baker *et al.* (2006) estimated that the islets of FFS would lose 15 to 65 percent of area under the median sea level rise scenario (0.48 m) and 26 to 99 percent of area under the maximum sea level rise scenario (0.88 m) by 2100. Sea level rise is expected to continue after 2100, and virtually all land at FFS would be submerged at a sea level rise of 2 m (Baker *et al.*, 2006). East Island, where 50 percent of nesting occurs at FFS (Balazs *et al.*, 2015), would persist the longest; however, it is not clear that displaced nesters from other areas of FFS (*i.e.*, the other 50 percent of nesting) would begin nesting at East Island. Dizon and Balazs (1982) conclude that once imprinted on a nesting beach, a green turtle is unlikely to switch its breeding habitat.

Using a simulation model, Tiwari *et al.* (2010) estimated carrying capacity at East Island under current conditions and based on predictions of sea level rise by 2100. With 30 percent loss of nesting habitat and a 20 percent increase in mortality (to simulate the effects of sea level rise and crowding), carrying capacity would be reached at 60,000 to 100,000 nests (Tiwari *et al.*, 2010). The model considered all available area on the island suitable for nesting (Tiwari *et al.*, 2010); however, Balazs (1980) reports that very few turtles have nested in 5 of 17 available areas at East Island, despite apparently suitable habitat. Therefore, while there appears to be adequate suitable habitat at East Island, it is uncertain how many turtles would use this habitat for nesting if their current nesting habitat were lost.

Reynolds *et al.* (2012) examined sea level rise scenarios of 0.0 to 2.0 m, focusing on mean high water, which is lower than the spring tide estimates used by Baker *et al.* (2006) and Tiwari *et al.* (2010). At FFS, they projected 12 percent land loss at 1.0 m sea level rise and 32 percent land loss at 2.0 m sea level rise, which would result in the complete submergence of five of the nine islets (Reynolds *et al.*, 2012).

Reynolds *et al.* (2012) concluded that the decreases in nesting areas at FFS are likely to limit nesting habitat for the green turtles if philopatry (*i.e.*, natal beach fidelity) prevents their dispersal. They also predicted that along the coastline, groundwater levels and turtle nesting density will likely change as a result of sea level rise and that these changes, along with increasing temperatures, would negatively impact green turtle nesting (Reynolds *et al.*, 2012). They identified the need for additional climate change adaptation strategies and planning for marine wildlife dependent on the terrestrial breeding habitats of FFS and Pearl and Hermes Atoll, which are likely to be inundated before 2100 (Reynolds *et al.*, 2012).

It must be noted that these studies used a passive, inundation or "bathtub" model, which is conservative and does not consider storm surges or the projected increases in storm intensity and frequency (Hawkes *et al.*, 2009). In addition, the flooding scenarios do not consider erosive recession of the shoreline causing land loss, long-shore drift redistribution of sediments (resulting in both gains and losses of land area), net permanent loss of sand volume offshore, and onshore sand deposition by overwash during high wave activity (Baker *et al.*, 2006).

These considerations appear to be important in Hawai'i, where historical shoreline changes (*i.e.*, coastal erosion) are one to two orders of magnitude greater than sea level rise (Romine *et al.*, 2013). In addition, erosion rates vary among the Hawaiian Islands as a result of sea level rise, sediment availability, anthropogenic changes, littoral processes, wave conditions, and coastal and nearshore geomorphology (Romine *et al.*, 2013). At 9 of 10 sites in the MHI, the shorelines are projected to retreat 1 to 24 m by 2050 and 4 to 60 m by 2100 (Anderson *et al.*, 2015). Sea level rise is likely to lead to doubling of the shoreline recession by 2050 (and 2.5 times by 2100) as compared to extrapolations based on historical erosion (Anderson *et al.*, 2015). In addition, changes in storminess, wave climate, sediment availability, and climate related modifications in reef geomorphology will enhance erosion and inundation of low-lying coastal areas (Anderson *et al.*, 2015).

The MHI may also be exposed to "coastal squeeze," *i.e.*, as sea level rises, the landward migration of nesting beaches (and available nesting habitat) is inhibited due to coastal development and beachfront barriers (Fish *et al.*, 2005; Fish *et al.*, 2008). Therefore, as one commenter suggests, habitat modification due to coastal development is likely to be exacerbated by sea level rise.

In addition to sea level rise, we considered the effects of increased temperatures (including nest failure and skewed sex ratios), ocean acidification, and the impact of sea level rise on the movement of hatchlings, oceanic juveniles, and adults. Hawkes *et al.* (2014) conclude that breeding ecology may be fundamentally affected by climate change and that altered thermal regimes may have the most dramatic and insidious effects on sea turtles. This is especially a concern in Hawai'i, where from 1990 to 2014, the sea surface temperature warmed an average of 0.034 °C annually (roughly three times the observed global average over this period), a change that is likely to result in the cessation of basking, an adaptive trait exhibited by turtles of the Central North Pacific DPS, by 2100 (Van Houtan *et al.*, 2015).

Comment 28: Two commenters requested exemptions to existing take prohibitions. Their comments suggested that the Services should make specific findings for each of the threatened DPSs that protective regulations are necessary and advisable. The State of Hawai'i DLNR recommended that the Services partner with DLNR and communities to develop appropriate exemptions to take prohibitions under section 4(d) of the ESA to allow for more flexible, responsive, and enhanced management.

Response: As noted in the proposed rule and explained further in response to *Comment 7*, longstanding protective regulations apply the prohibitions of Section 9 (including the "take" prohibitions) to threatened sea turtles, with limited exceptions, and continue to remain in effect (50 CFR 17.42(b), 223.205, 223.206, and 223.207). Modifications to such regulations are beyond the scope of this rule, which finalizes the listing determinations for green turtle DPSs. The Services may extend the prohibitions of section 9 through protective regulations that apply generally to a group of threatened species and are not required to make species-specific determinations as new species are listed. *Sweet Home Chapter of Communities for a Great Oregon* v. *Babbitt*, 1 F.3d 1 (D.C. Cir. 1993), *modified on other grounds on reh'g*, 17 F.3d 1463 (D.C. Cir. 1994), *rev'd*, 515 U.S. 687 (1995). While we noted the existence of the existing regulations in the proposed rule to apprise the public of the full regulatory landscape for green turtles, we did not undertake a review, extension or modification of those rules, which are entirely separate. This is consistent with the approach we took for the listing determinations of nine DPSs of loggerhead sea turtles (76 FR 58868, September 22, 2011).

Comment 29: We received several comments on the recovery (or lack thereof) of the Central North Pacific DPS. Several commenters stated that the DPS was recovered; however, one commenter stated that the DPS has not recovered because it has not met the recovery criteria.

Response: Please see our response to *Comment 16.* Because the commenters raised the issue of whether the species had met its recovery criteria, we provide the following information.

Prior to the identification and proposed listing of the Central North Pacific DPS, the Services published the Recovery Plan for U.S. Pacific Populations of the Green Turtle (*i.e.*, the Recovery Plan; NMFS and USFWS, 1998). The Hawaiian population was included in the Recovery Plan. One of the recovery criteria has been met: We have identified all regional stocks to source beaches. The other recovery criteria have not been met. The DPS does not average 5,000 females nesting annually. Although the nesting population at East Island has increased over the past four decades, 25 years of monitoring data are not available for other nesting beaches. There are numerous threats at key foraging areas, where population trend data are not available. First priority tasks that have not been implemented include: Determination of distribution and abundance of post-hatchlings; assessment and prevention of degradation of reefs by boating and diving activities; and prevention of degradation of reefs by pollution, coastal erosion, siltation, and blasting. There is no management plan to maintain sustained populations of turtles in the absence of ESA protections, and there are no international agreements to reduce bycatch (and bycatch mortality) in foreign longline fisheries.

Comment 30: We received several comments on the carrying capacity of the Central North Pacific DPS. Several commenters stated that the DPS is overpopulated or has reached carrying capacity (*K*), citing Chaloupka and Balazs (2007) or similar publications and disagreeing with Kittinger *et al.* (2013).

Response: Balazs *et al.* (2015) summarized all existing data and knowledge on the demographic variables of Hawaiian green turtles. After reviewing all data, from 1973 to 2012, they concluded that the Hawaiian green turtle is not at carrying capacity (Balazs *et al.*, 2015). Specifically, they found that the population growth rates from 1973 to 2003 (Chaloupka *et al.*, 2008), 1973 to 2004 (Chaloupka and Balazs, 2007), and 1973 to 2012 "are statistically indistinguishable, indicating that the last 10 years have not demonstrated any slowing of population growth or negative density dependence as some predicted (*e.g.*, Chaloupka and Balazs, 2007)" (Balazs *et al.*, 2015). The authors concluded that the population is "still growing at a robust rate and underscore historical analyses (*e.g.*, Kittinger *et al.*, 2013; Van Houtan and Kittinger, 2014) that suggest the population was significantly more abundant historically" (Balazs *et al.*, 2015). Because the Balazs *et al.* (2015) paper reviews all current and historical demographic data, we consider it the best available scientific data. We provide the following information to further explain this complex topic and resolve any perceived disagreement regarding available data.

There have been numerous studies on carrying capacity in the Hawaiian green turtle population, focusing on foraging, nesting site, and overall carrying capacity (*e.g.*, Balazs and Chaloupka, 2004a; 2004b; 2006; Chaloupka and Balazs, 2007; Snover *et al.*, 2008; Tiwari *et al.*, 2010; Wabnitz *et al.*, 2010). Bjorndal *et al.* (2000) were the first to evaluate compensatory responses resulting from density-dependent effects for a green turtle population (*i.e.*, sea turtles foraging in a Bahamian bay of approximately 20 km²). They found three lines of evidence to support a density-dependent effect: Significant inverse correlation between population density and mean annual growth rate; correlations between condition index and mean annual growth rates (positive) and population density (negative); and the population abundance fluctuated around carrying capacity at levels likely to experience density-dependent effects (*i.e.*, *K* of approximately 100 turtles; Bjorndal *et al.*, 2000). Balazs and Chaloupka (2004a) applied this approach to five foraging areas in Hawai'i: Midway Atoll; Kane'ohe Bay, O'ahu; Pala'au, Moloka'i; and Kiholo Bay and Punalu'u Bay, Hawai'i. They found significant, long-term declines in size-specific growth rates at Pala'au, Kiholo Bay, and Punalu'u Bay, which may reflect limited food availability or nutritional quality (Balazs and Chaloupka, 2004a). Balazs and Chaloupka (2004a) did not state that carrying capacity had been reached at any location; instead, they interpreted these data to mean that carrying capacity for Kiholo and Punalu'u "might" have been reached. The authors concluded that density-dependent effects are not well understood and warrant further investigation (Balazs and Chaloupka, 2004a). Wabnitz *et al.* (2010) used an ecosystem model to confirm that the green turtle aggregation has reached carrying capacity at Kaloko-Honokōhau National Historical Park. Based on these studies, we conclude that foraging carrying capacity has likely been reached at this one location on the Big Island of Hawai'i, which may be ecologically representative of green turtle habitats spanning 100 km on the west coast of that island (Balazs *et al.*, 2015). This does not, however, mean that green turtles have reached carrying capacity in their foraging habitat throughout the Hawaiian Archipelago. Numerous publications identify current or historically important foraging areas on: Kaua'i (Princeville, northwestern coastal areas of Na Pali, and southern coastal areas from Kukuiula to Makahuena Point); O'ahu (Kawela Bay, Kailua and Kaneohe Bays, northwestern coastal areas from Mokuleia to Kawailoa, Maunalua Bay, West Beach, and Sandy Beach); Moloka'i (southern coastal areas from Kamalo to Halena and Pala'au); Lana'i (northern and northeastern coastal areas bordering Kalohi and Auau Channels, Keomuku, Kuahua, and Polihua Beach); Maui (Hana District and Paia, Kahului Bay, Honokowai, Maliko Bay, and Olowalu); Hawai'i (Kau and North Kohala Districts, and Kapoho); and the NWHI (Necker Island, FFS, Lisianski Island, Pearl and Hermes Reef, Laysan Island, Midway Atoll, and Kure Atoll) (Balazs, 1980; Balazs, 1987; Arthur and Balazs, 2008). Furthermore, green turtles not only forage on native seagrass and algal species but also thrive on nonnative species (Arthur and Balazs, 2008; Russell and Balazs, 2009; McDermid *et al.*, 2015). Finally, if foraging carrying capacity were reached, we would expect nutritional constraints to lead to reduced nesting frequency due to density-dependent effects resulting from competition for limited food resources (Bjorndal *et al.*, 2000). However, the 3 to 4 year female remigration interval has remained constant since 1973 (Balazs and Chaloupka, 2004b; 2006; Balazs *et al.*, 2015), indicating that females do not spend additional time foraging before returning to nest. For these reasons, we conclude that the DPS has not reached foraging carrying capacity.

One study has also considered nesting carrying capacity. Tiwari *et al.* (2010) used a simulation model to estimate carrying capacity on the nesting beach of East Island, FFS. They found that East Island is well below carrying capacity and is capable of supporting a larger nesting population (Tiwari *et al.*, 2010). Therefore, we conclude that the DPS has not reached nesting carrying capacity.

Other studies considered overall carrying capacity (Balazs and Chaloupka, 2004a; 2006; Chaloupka and Balazs, 2007; Snover *et al.*, 2008). Three publications on modeling cited the long-term increase in the abundance of nesting females at East Island and a constant level of new recruits as possible evidence of nearing carrying capacity (Balazs and Chaloupka, 2004a; 2006; Chaloupka and Balazs, 2007); however, these studies were not conclusive and did not claim that the population was at carrying capacity (Balazs and Chaloupka, 2004a; 2006; Chaloupka and Balazs, 2007; Snover *et al.*, 2008). There were also several issues with these analyses. For example, Chaloupka and Balazs (2007) indicated the data were uninformative for *K* and that *K* was estimated with significant uncertainty. Furthermore, their model did not indicate that the population was near *K* because the plot of nester abundance showed an exponentially growing population (Snover *et al.*, 2008).

Finally, since the original consideration of carrying capacity in 2004, the abundance of nesting females at East Island has continued to increase from an estimated average of 338 nesting females (2000–2003) to an estimated average of 464 nesting females (2009–2012; Humburg and Balazs, 2014). Had carrying capacity been reached in 2004, we would have expected nesting abundance and population growth rates to level off or decrease by now.

Kittinger *et al.* (2013) analyzed data from middens (*i.e.*, domestic waste sites) and observational data from historical sources, including interviews with community elders who described the harvest of nesting turtles at Kaua'i beaches prior to 1960. It is unlikely that the community elders would have confused nesting and basking turtles, as suggested by some commenters. The *Hawaiian Gazette* (July 19, 1912) cited Judge Kapoikai watching "baby turtles scuttle down the beach" in Maui; hatchlings are not likely to be confused with other life stages. These examples are indicative of nesting in the MHI prior to ESA protections. Van Houtan and Kittinger (2014) analyzed nearly three decades (1948 to 1974) of data on commercial landings data from a green turtle fishery in the MHI. These data indicate that the small-scale fishery and local market demand were key factors in the decline of Hawaiian green turtles, which were already significantly depleted by prior exploitation (Van Houtan and Kittinger, 2014).

In summary, we conclude that historically the DPS was significantly more abundant and has not yet reached foraging, nesting, or overall carrying capacity.

Comment 31: One commenter indicated that the determination on the Central North Pacific DPS is inconsistent with the 2012 International Union for Conservation of Nature (IUCN) Red List of Threatened Species™ (*i.e.,* Red List) assessment, which categorized the Hawaiian subpopulation of green turtles as "least concern."

Response: Species classifications under the ESA and Red List are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are not the same, nor is the legal effect.

Unlike the ESA, the Red List is not a statute and is not a legally binding or regulatory instrument. It does not include legally binding requirements, prohibitions, or guidance for the protection of threatened (*i.e.,* critically endangered, endangered, or vulnerable) taxa (IUCN, 2012). Rather, it provides taxonomic, conservation status, and distribution information on species. The Red List is based on a system of categories and criteria designed to determine the *relative* risk of extinction (*http://www.iucnredlist.org/about/introduction*), classifying species in one of nine categories, as determined via quantitative criteria, including population size reductions, range reductions, small population size, and quantitative extinction risk. The ESA requires the Services to list species if they are endangered or threatened by any or a combination of the section 4(a)(1) factors (16 U.S.C. 1533(a)(1)), as based on the best available scientific and commercial data, which may include a qualitative threats analysis.

Thus, the ESA and Red List are inherently different. To the extent that the information described within Red List is relevant to our determination, we do not agree that the DPS "is approaching full recovery to pre-exploitation levels" (IUCN, 2012). The IUCN cites the modeling study by Chaloupka and Balazs (2007), which has been refuted by more recent and complete data (Balazs *et al.,* 2015), which we consider to be the best available scientific data. In response to *Comment 30,* we identify the problems with the Chaloupka and Balazs (2007) study. Their pre-exploitation estimate of 320,000 turtles is likely an underestimate because it is based solely on small-scale fishery landings from 1944 to 1973; however, broad-scale commercial exploitation of the population began in the early 19th century and may have been quite extensive (Amerson, 1971; Van Houtan and Kittinger 2014). In addition, traditional exploitation occurred for centuries prior (Chaloupka and Balazs, 2007; Kittinger *et al.,* 2013). Therefore, it is likely that the DPS was significantly more abundant historically (Kittinger *et al.,* 2013; Van Houtan and Kittinger, 2014; Balazs *et al.,* 2015).

We agree with the IUCN's identification of the following threats to the DPS: Restricted location (*i.e.,* utilization of one rookery); erosion and habitat loss throughout the NWHI; climate impacts; illegal harvesting; FP, which causes debilitating tumors of the skin and internal organs; coastal development and urbanization, fishing line ingestion or entanglement from recreational shore based fisheries, entanglement in gill nets, vessel collisions, miscellaneous hazards such as spear wounds; and climate change (increasing sea surface temperature and increasing intensity and frequency of severe storms) (*http://www.iucnredlist.org/details/16285718/0*). Because of these factors, the Central North Pacific DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Comment 32: One commenter stated that the recapture of three Central North Pacific turtles in Japan, the Marshall Islands, and the Philippines out of 7,360 total recaptures signifies adequate gene flow to homogenize populations (*i.e.,* the populations are not genetically discrete).

Response: We have not detected any shared mtDNA haplotypes between the Central North Pacific DPS and the Central West Pacific or the East Indian-West Pacific DPSs. If gene flow had been adequate to homogenize the DPSs, we would expect shared haplotypes and consistent haplotypic frequencies in these DPSs. Furthermore, in 50 years of extensive nesting surveys in the Hawaiian Archipelago, no recaptures or haplotypes from the Central West or East Indian-West Pacific DPSs have been encountered.

Comment 33: Several commenters stated that green turtles were consuming too much limu (*i.e.,* Hawaiian algae).

Response: The extent of turtle consumption of limu is not relevant to our listing determination because it does not represent a threat to turtles; however, we believe a fuller understanding of this issue is important to promoting conservation of green turtles and dispelling misinformation. We provide the following information because reductions in limu are likely caused by other species. Nonnative algae pose one of the greatest threats to native algae by competing for space. Additional threats to limu include: storm water discharges, pollution, development, and overharvesting by humans (Wianecki, 2010; Lapointe and Bedford, 2011). At Kaloko-Honokōhau National Historical Park, Wabnitz *et al.* (2010) determined that sea urchins have the greatest impact (45 percent) on algal resources, followed by herbivorous fish (14.4 percent), with green turtles only accounting for 0.2 percent of total herbivory consumption.

Green turtles are selective foragers that target specific species (Balazs, 1980). Only two of these species (*U. fasciata* and *C. edule,* which are both common; Abbott, 1984) are favored by humans. In fact, green turtles may provide benefits to limu by consuming nonnative algae (Arthur and Balazs, 2008; Russel and Balazs, 2009).

Comment 34: One commenter stated that the increase in green turtles is linked to an increase in sharks and shark attacks on humans. One commenter stated that green turtles damage coral in Kaneohe Bay, Hawai'i.

Response: As we noted in our response to *Comment 33,* our listing determination must be based solely on a review of the status of the species; extraneous considerations are not relevant. Nevertheless, the best available scientific and commercial data do not link the increasing abundance of green turtles to increasing shark abundance or attacks (*http://www.honolulumagazine.com/Honolulu-Magazine/February-2016/Why-Are-There-So-Many-Shark-Attacks-in-Hawaii/*). Furthermore, green turtles likely improve the overall health of coral reefs in Kaneohe Bay by controlling the overgrowth of nonnative algae (Pandolfi *et al.,* 2005; Russel and Balazs, 2009).

Comments on the East Pacific DPS

Comment 35: The Instituto del Mar del Perú suggested breaking the East Pacific DPS into two DPSs and listing the southeast Pacific as endangered for the following reasons: (1) While there is an increasing trend at Michoacán nesting beaches (Delgado-Trejo and Alvarado-Diaz, 2012), there have not been substantial increases at Galápagos nesting beaches in the past 15 years (IAC, 2011, 2012, 2013, 2014); (2) Peru lists the species as endangered (D.S. No. 004–2014–MINAGRI) and prohibits hunting, capture, possession, and transportation of specimens, products and/or byproducts; in addition, Perú is a signatory of several international agreements for the conservation of sea turtles that developed their work plan and resolutions on the basis of the IUCN Red List category of endangered (Seminoff, 2004); (3) southeast Pacific turtles face numerous threats including bycatch, harvest, illegal trade of turtle meat, oil, and derivatives (Alfaro Shigueto *et al.*, 2010, 2011; de Paz et al, 2002); and (4) increasing threats include coastal development, artisanal fisheries, and aquaculture, which occur close to foraging areas and cause habitat degradation.

Response: We appreciate the Instituto del Mar del Perú's comments and efforts to conserve sea turtles. For differences between the ESA and IUCN Red List, please see *Comment 31*. Turtles of the East Pacific DPS share phenotypic traits, including size (*i.e.*, small) and color (*i.e.*, black), that are not found in other Pacific DPSs. They share haplotypes from Clade VIII and do not exhibit haplotypes from other clades (Seminoff *et al.*, 2015). There is significant genetic structure within the DPS (*i.e.*, four regional stocks; Seminoff *et al.*, 2015); however, the divergence among stocks is much less than the divergence among DPSs, as indicated by nuclear (Roden *et al.*, 2013) and mtDNA (Seminoff *et al.*, 2015). Furthermore, the most significant differences do not occur between turtles nesting at Mexican and Galápagos beaches, but rather between the turtles nesting at the Revillagigedos Islands (Mexico) and all others (Seminoff *et al.*, 2015). Genetically, females nesting at Michoacán (Mexico) are more similar to females nesting in the Galápagos Islands than to those nesting at the Revillagigedos Islands (Seminoff *et al.*, 2015). Satellite tracking indicates that turtles nesting in Michoacán, Costa Rica, and the Galápagos Islands converge at foraging areas in Central America (Hart *et al.*, 2015), and at least one Michoacán turtle was recovered as far south as Colombia (Alvarado-Díaz and Figueroa, 1990). Based on the best available scientific and commercial data which indicates connectivity within the DPS, we conclude that the East Pacific DPS is discrete and significant and should not be further divided.

Conservation efforts have led to increasing abundance at numerous nesting sites throughout the range of the DPS. In addition to the increasing trends at Michoacán, we found stable to slightly increasing nesting trends at Galápagos nesting beaches, which host the second largest nesting aggregation of the DPS (Seminoff *et al.*, 2015). We do not find that the East Pacific DPS is presently in danger of extinction; however, it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range due to habitat loss and degradation, overexploitation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, boat strikes, red tide poisoning, and climate change. Therefore, we finalize our proposal to list the East Pacific DPS as threatened under the ESA.

Summary of Changes From the Proposed Rule

We make the following changes from the proposed rule:

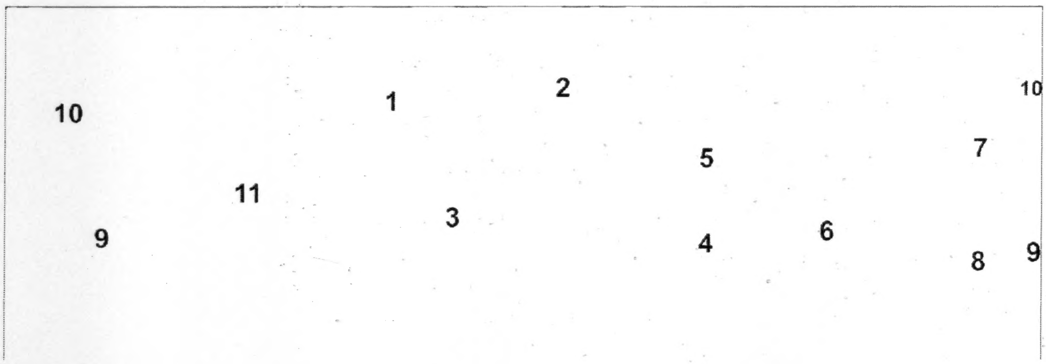
- We change the boundaries of the ranges for the North and South Atlantic DPSs because all islands of the U.S. Virgin Islands (not just St. Croix) should be included in the range of the South Atlantic DPS, as indicated by genetic and other data presented in the Status Review Report.
- In the proposed rule, we erroneously listed the California and Oregon border as 41° N.; we remove the reference to the California and Oregon border, however, 41° N. remains the northern boundary for the range of the East Pacific DPS.
- We corrected typographical errors in the listing tables and throughout the preamble, including correcting the citation to the existing critical habitat designation for the North Atlantic DPS, at 50 CFR 226.208.
- We include information on the National Colombia Programme for Conservation of Marine and Continental Turtles in our consideration of conservation efforts for the South Atlantic and East Pacific DPSs.
- We indicate that the BIOT, located within the range of the Southwest Indian DPS, protects green turtles and their habitat; however, conservation efforts are not sufficient to adequately reduce all threats (Mortimer and Day, 1999).
- We reviewed, and incorporate as appropriate, scientific data from references that were not included in the Status Review Report and proposed rule. We include the following references, which together with previously cited references, represent the best available scientific and commercial data; however, these new references do not present significant new findings that change any of our proposed listing determinations: Benaka *et al.*, 2013; Adimey *et al.*, 2014; Bourjea *et al.*, 2014; Brei *et al.*, 2014; Carreras *et al.*, 2014; Casale and Mariani, 2014; Dutton *et al.*, 2014a; Dutton *et al.*, 2014b; González Carman *et al.*, 2014; Hays *et al.*, 2014; Keller *et al.*, 2014; Lagueux *et al.*, 2014; Naro-Maciel *et al.*, 2014a; Naro-Maciel *et al.*, 2014b; Ng *et al.*, 2014; Read *et al.*, 2014; Schuyler *et al.*, 2014; Senko *et al.*, 2014; Shamblin *et al.*, 2014; Van Houtan *et al.*, 2014; Balazs *et al.*, 2015; Baudouin *et al.*, 2015; Brost *et al.*, 2015; Cavallo *et al.*, 2015; Esteban *et al.*, 2015; Guilder *et al.*, 2015; Hart *et al.*, 2015; Jourdan and Fuentes, 2015; Katsanevakis *et al.*, 2015; Mancini *et al.*, 2015; Rhodes, 2015; Ruiz-Izaguirre *et al.*, 2015; Santidrián Tomillo *et al.*, 2015; Santos *et al.*, 2015b; Stokes *et al.*, 2015; Stringell *et al.*, 2015; Ullmann and Stachowitsch, 2015; Van Houtan *et al.*, 2015; Wedemeyer-Strombel *et al.*, 2015; Wilcox *et al.*, 2015; Work *et al.*, 2015; Yang *et al.*, 2015; Martin *et al.*, 2016; Halley *et al.*, in review; Summers *et al.*, in progress; NMFS, in progress.

Identification of DPSs

The comments that we received on the proposed rule did not change our conclusions regarding the identification of DPSs. We reviewed relevant and recently available scientific data that were not included in the Status Review Report and proposed rule (Carreras *et al.*, 2014; Casale and Mariani, 2014; Dutton *et al.*, 2014a; Dutton *et al.*, 2014b; Hays *et al.*, 2014; Naro-Maciel *et al.*, 2014a; Naro-Maciel *et al.*, 2014b; Ng *et al.*, 2014; Read *et al.*, 2014; Shamblin *et al.*, 2014; Baudouin *et al.*, 2015; Esteban *et al.*, 2015; Hart *et al.*, 2015; Mancini *et al.*, 2015; Stokes *et al.*, 2015; Yang *et al.*, 2015). The identification of fine-scale genetic structure or mixing at foraging areas for some DPSs does not change our findings for the proposed DPSs. Based on the best available scientific and commercial data, we conclude that the DPSs identified in the proposed rule are discrete and significant. Therefore, we incorporate herein all information on the identification of DPSs in the Status Review Report and proposed rule, with the following exception as discussed above: We changed the boundary between the North and South Atlantic DPSs so that all islands of the U.S. Virgin Islands (not just St. Croix) would be included in the South Atlantic DPS.

In summary, we applied our joint DPS policy (61 FR 4722, February 7, 1996) to identify 11 discrete and significant DPSs: North Atlantic, Mediterranean, South Atlantic, Southwest Indian, North Indian, East Indian-West Pacific, Central West Pacific, Southwest Pacific, Central South Pacific, Central North Pacific, and East Pacific (Figure 1).

Figure 1. Map of the green turtle DPSs: (1) North Atlantic, (2) Mediterranean, (3) South Atlantic, (4) Southwest Indian, (5) North Indian, (6) East Indian-West Pacific, (7) Central West Pacific, (8) Southwest Pacific, (9) Central South Pacific, (10) Central North Pacific, and (11) East Pacific.



North Atlantic DPS

The comments that we received on the North Atlantic DPS and additional information that became available since the publication of the proposed rule did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the North Atlantic DPS provided in the Status Review Report and proposed rule, with the following exceptions: The boundary of the DPS (which was changed to exclude all islands of the U.S. Virgin Islands), and the application of the critical risk threshold from the Status Review Report (which, as we explained in the proposed rule, does not directly correlate with the ESA definitions of "endangered" and "threatened"). The following represents a brief summary of that information.

The range of the DPS extends from the boundary of South and Central America, north along the coast to include Panama, Costa Rica, Nicaragua, Honduras, Belize, Mexico, and the United States. It extends due east across the Atlantic Ocean at 48° N. and follows the coast south to include the northern portion of the Islamic Republic of Mauritania (Mauritania) on the African continent to 19° N. It extends west at 19° N. to the Caribbean basin to 65.1° W., then due south to 14° N., 65.1° W., then due west to 14° N., 77° W., and due south to 7.5° N., 77° W., the boundary of South and Central America. It includes Puerto Rico, the Bahamas, Cuba, Turks and Caicos Islands, Republic of Haiti, Dominican Republic, Cayman Islands, and Jamaica. The North Atlantic DPS includes the Florida breeding population, which was originally listed as endangered under the ESA (43 FR 32800, July 28, 1978).

Demographic Parameters for the North Atlantic DPS

The DPS exhibits high nesting abundance, with an estimated total nester abundance of 167,424 females at 73 nesting sites. More than 100,000 females nest at Tortuguero, Costa Rica, and more than 10,000 females nest at Quintana Roo, Mexico. Nesting data indicate long-term increases at all major nesting sites. There is little genetic substructure within the DPS, and turtles from multiple nesting beaches share common foraging areas. Nesting is geographically widespread and occurs at a diversity of mainland and insular sites.

Section 4(a)(1) Factors for the North Atlantic DPS

Nesting beaches are degraded by coastal development, coastal armoring, beachfront lighting, erosion, sand extraction, and vehicle and pedestrian traffic. Foraging habitat is degraded by pollution (including oil spills, agricultural and residential runoff, and sewage), propeller scarring, anchor damage, dredging, sand mining, marina construction, and beach nourishment. The harvest of green turtles and eggs remains legal in several countries (*e.g.*, Lagueux *et al.*, 2014), and illegal harvest occurs in many areas. FP is a chronic, often lethal disease that affects turtles throughout the range of the DPS, and (as discussed in a summit held since the publication of the proposed rule) especially in areas with some degree of environmental degradation resulting from altered watersheds (NMFS, in progress). It may be increasing in prevalence in some areas (*e.g.*, Stringell *et al.*, 2015). As recently described by Brost *et al.* (2015), predation is one of the main sources of egg and hatchling mortality in some areas. Jaguars also prey on nesting females, as recently described by Guilder *et al.* (2015). Though numerous regulatory mechanisms apply to the DPS, many are inadequate due to limited implementation and enforcement. There has been one regulatory change since the publication of the proposed rule, which reduces the inadequacy of regulatory mechanisms: The State of Louisiana repealed the prohibition on enforcement of turtle excluder device regulations (LA HB668, July 1, 2015). Fisheries bycatch in artisanal and industrial fishing gear (*e.g.*, gill net, trawls, and dredges) results in substantial mortality (*e.g.*, Benaka *et al.*, 2013). Periodic dredging of sediments from navigational channels can also result in incidental mortality of sea turtles (*http://el.erdc.usace.army.mil/seaturtles/takes.cfm?Type=Total&Code=Table*). Vessel strikes are a significant and increasing source of mortality in the U.S. Atlantic and Gulf of Mexico and likely in other locations. In some areas, there has been an increase in strandings due to entanglement in marine debris and the ingestion of plastics, as recently described by Adimey *et al.* (2014), which causes blockage in the gut and dilutes the nutritional contribution of the diet. Cold stunning, the hypothermic reaction that occurs when sea turtles are exposed to prolonged cold water temperatures, occurs regularly throughout the range of the DPS and may result in a UME. Oil spills may also result in a UME. The *Deepwater Horizon* oil spill was particularly harmful to post-hatchlings and surface-pelagic juveniles by temporarily destroying their *Sargassum* habitat (Powers *et al.*, 2013) and resulting in the ingestion of contaminants (Witherington *et al.*, 2012). Climate change is likely to have a negative effect on the DPS. Sea level rise is likely to alter green turtle nesting habitat and reduce nesting success. Increased sand temperature is likely to result in skewed sex ratios and lethal incubation conditions, as recently described by Santos *et al.* (2015a).

Conservation Efforts for the North Atlantic DPS

Conservation efforts include bycatch reduction measures, nesting beach acquisitions, and nest protection programs to reduce harvest and predation. Numerous initiatives, such as the Colombia National Programme for the Conservation of Marine and Continental Turtles, promote education, conservation, and outreach. The recovery of the DPS is dependent on ESA protections and those provided by local, State, and foreign laws, some of which may have been triggered by the original ESA listing. Though ESA protections would be lost if the DPS were not listed under the ESA, it is unclear whether local, State, and foreign laws would remain in place.

Extinction Risk Analysis for the North Atlantic DPS

The high nesting abundance, increasing trends, connectivity, and spatial diversity provide the DPS with some resilience against current threats (*i.e.*, the threats have not prevented positive population growth in recent years). The DPS is threatened by several factors: The current and projected destruction and modification of its habitat; legal and illegal harvest of turtles and eggs; disease and predation; inadequacy of regulatory mechanisms to regulate the underlying threats; and other factors (*i.e.*, fisheries bycatch, channel dredging, marine debris, cold stunning, and climate change). Though beneficial, the conservation efforts do not adequately reduce the threats. Based on the above information, we conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because numerous threats remain, several of which are likely to increase within the foreseeable future; all threats are likely to increase if ESA protections are lost, resulting in curtailed or reversed population trends. We conclude that the North Atlantic DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the North Atlantic DPS

For the above reasons, we list the North Atlantic DPS as a threatened species under the ESA.

Mediterranean DPS

The comments that we received on the Mediterranean DPS and additional information that became available since the publication of the proposed rule did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the Mediterranean DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the DPS includes the Mediterranean Sea (excluding the Black Sea), with the Strait of Gibraltar as its western boundary.

Demographic Parameters for the Mediterranean DPS

The DPS exhibits low abundance, with an estimated total nester abundance of 404 to 992 females at 32 sites. The DPS is severely depleted relative to historical levels; however, five of seven nesting sites indicate slightly increasing trends. Connectivity is high (*i.e.*, little to no genetic substructure), but nesting site diversity is low.

Section 4(a)(1) Factors for the Mediterranean DPS

Nesting habitat is destroyed or modified by coastal development, construction, beachfront lighting, sand extraction, beach erosion, vehicular and pedestrian traffic, and beach pollution. Fishing and pollution result in the destruction and modification of foraging habitat. The harvest of turtles and eggs contributed to the historical decline of this DPS and continues in several areas. Numerous species prey on eggs and hatchlings. Many international and national regulatory mechanisms exist; however, fisheries bycatch and tourism impacts are poorly regulated. Fisheries bycatch results in substantial mortality and is a major threat to the DPS. Vessel activity and strikes result in mortality, injury, and abandoned nesting attempts. Marine debris is a major concern. Climate change is likely to alter thermal sand characteristics; in some areas, hatchling sex ratios are already highly female biased (up to 95 percent).

Conservation Efforts for the Mediterranean DPS

Conservation efforts include protection of nesting beaches, removal of marine debris, and establishment of marine protected areas. In a recent study, Ullmann and Stachowitsch (2015) identified 49 stranding response (*i.e.*, rescue) centers, stations, and institutions throughout the Mediterranean; however, communication among such facilities is limited, and there are gaps in coverage.

Extinction Risk Analysis for the Mediterranean DPS

As a result of low nesting abundance (concentrated primarily in one area), weak population growth rates, and low diversity of nesting sites, the DPS has little resilience to threats, which include: Habitat loss and degradation, overexploitation, predation, inadequate regulatory mechanisms, fisheries bycatch, vessel traffic, marine debris, and climate change. Although they are beneficial, the conservation efforts do not adequately reduce threats. We conclude that the Mediterranean DPS is in danger of extinction throughout all or a significant portion of its range.

Listing Determination for the Mediterranean DPS

For the above reasons, we list the Mediterranean DPS as an endangered species under the ESA.

South Atlantic DPS

The comments that we received on the South Atlantic DPS and additional information that became available since the publication of the proposed rule did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the South Atlantic DPS provided in the Status Review Report and proposed rule, with the following exceptions: the boundary of the DPS (which was changed to include all islands of the U.S. Virgin Islands), and the application of the critical risk threshold from the Status Review Report (which, as we explained in the proposed rule, does not directly correlate with the ESA definitions of "endangered" and "threatened"). The following represents a brief summary of that information.

The range of the South Atlantic DPS begins at the border of Panama and Colombia at 7.5° N., 77° W., heads due north to 14° N., 77° W., then east to 14° N., 65.1° W., then north to 19° N., 65.1° W., and along 19° N. latitude to Mauritania in Africa, to include the U.S. Virgin Islands in the Caribbean. It extends along the coast of Africa to South Africa, with the southern border being 40° S. latitude.

Demographic Parameters for the South Atlantic DPS

The DPS exhibits high nesting abundance, with an estimated total nester abundance of 63,332 females. Two nesting sites have greater than 10,000 nesting females: Poilão, Guinea-Bissau and Ascension Island, UK (Weber *et al.*, 2014). Nesting trends are increasing at the 14 sites where abundance data are available. Within the DPS, there is little genetic substructure, and turtles share important foraging areas. Nesting is geographically widespread and diverse, occurring along the western coast of Africa, on Caribbean and South Atlantic islands, and along eastern South America.

Section 4(a)(1) Factors for the South Atlantic DPS

Nesting habitat is destroyed or modified by coastal development and construction, placement of erosion control structures and other barriers to nesting, beachfront lighting (*e.g.*, Brei *et al.*, 2014), vehicular and pedestrian traffic, sand extraction, beach erosion, beach sand placement, beach pollution, removal of native vegetation, and planting of non-native vegetation. Foraging habitats are degraded by pollution, including agriculture and industrial runoff, and anchor damage to seagrass beds. The harvest of turtles and eggs contributed to the historical declines of the DPS and continues in some areas, legally and illegally. FP is highly variable in its presence and severity throughout the range of the DPS. Predators eat eggs, hatchlings, and nesting females. Throughout the range of the DPS, laws protecting sea turtles and their nesting habitats are implemented to varying degrees, but regulatory mechanisms to address fisheries bycatch are limited. Turtles are incidentally captured throughout the South Atlantic DPS in pelagic and demersal longlines, drift and set gill nets, bottom and mid-water trawls, fishing dredges, pound nets and weirs, haul and purse seines (*e.g.*, Bourjea *et al.*, 2014), pots and traps, and hook and line gear. There is a high prevalence of marine debris and plastic ingestion (*e.g.*, González Carman *et al.*, 2014). Sea level rise and increased storm frequency and intensity are likely to eliminate the functionality of nesting beaches on low-lying islands. Some beaches will likely experience lethal incubation temperatures that will result in the complete loss of hatchling cohorts.

Conservation Efforts for the South Atlantic DPS

Most nations in South America, the Caribbean, and Africa have national legislation or programs sponsored by state governments, local communities, academic institutions, and organizations to protect sea turtles and their nesting and foraging habitats. Conservation efforts at the primary nesting beaches, such as Ascension Island, include legal prohibitions as well as extensive monitoring, outreach, and research (*http://www.seaturtle.org/mtrg/projects/tukot/ascension.shtml*).

Extinction Risk Analysis for the South Atlantic DPS

As a result of the high population abundance, increasing nesting trend, and diverse nesting sites, the DPS is somewhat resilient to current threats, which include: Habitat loss and degradation, overexploitation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, oil exploration and extraction, and climate change. The conservation efforts vary in consistency and efficacy throughout the range of the DPS and do not adequately mitigate all threats. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because numerous threats remain, some of which are likely to increase within the foreseeable future; the loss of ESA protections would further exacerbate all threats. We conclude that the DPS is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the South Atlantic DPS

For the above reasons, we list the South Atlantic DPS as a threatened species under the ESA.

Southwest Indian DPS

The comments that we received on the Southwest Indian DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the Southwest Indian DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the Southwest Indian DPS has as its western boundary the shores of continental Africa from the equator, just north of the Kenya-Somalia border, south to the Cape of Good Hope (South Africa), and extends south from there along 19° E. longitude to 40° S., 19° E. Its southern boundary extends along 40° S. latitude from 19° E. to 84° E., and its eastern boundary runs along 84° E. longitude from 40° S. latitude to the equator. Its northern boundary extends along the equator from 84° E. to the continent of Africa just north of the Kenya-Somalia border.

Demographic Parameters for the Southwest Indian DPS

The DPS exhibits high abundance, with an estimated total nester abundance of 91,059 females at 15 nesting sites (four of which host more than 10,000 females). Nesting data at these mostly protected beaches indicate increasing trends. Within the DPS, there is a moderate degree of genetic substructure (*i.e.*, at least two stocks), with connectivity between proximate sites. The high diversity of nesting habitat includes insular and continental beaches.

Section 4(a)(1) Factors for the Southwest Indian DPS

Nesting beaches are threatened by increased tourism and artificial lighting. Foraging habitats are degraded by development of the coastline, dredging, land-fill, sedimentation, and sand extraction. Legal and illegal harvest of turtles and eggs persists throughout the DPS. Poaching of nesting females has led to declines at some beaches, and foraging turtles are heavily poached in several areas. Existing regulatory mechanisms to address poaching and bycatch are often inadequately implemented and/or enforced, as demonstrated by the high level of illegal harvest and bycatch within this DPS. The DPS is threatened by bycatch in demersal and pelagic longlines, trawls, gill nets, and purse seines (*e.g.*, Bourjea *et al.*, 2014). Sea level rise and increasing storm events (as a result of climate change) are likely to reduce nesting habitat throughout the range of the DPS because much of the nesting occurs at low-lying islands and atolls.

Conservation Efforts for the Southwest Indian DPS

Several regional initiatives have promoted conservation, management, research and education throughout the range of the DPS. Other multinational programs and national laws protect sea turtles. For example, Mortimer and Day (1999) state that green turtles and nesting habitat in the Chagos Archipelago are well protected by the BIOT administration (Mortimer and Day, 1999) and a large marine protected area (Hays *et al.*, 2014); however, monitoring and conservation efforts are not sufficient to adequately reduce all threats.

Extinction Risk Analysis for the Southwest Indian DPS

The high nesting abundance, increasing nesting trends, and spatial and genetic diversity of the DPS provide some resilience to threats, which include: Habitat loss and degradation, overexploitation of eggs and turtles, inadequate regulatory mechanisms, fisheries bycatch, and climate change. Despite many beneficial conservation efforts, poaching and bycatch remain major threats. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because of the high levels of harvest and bycatch, in the context of increasing impacts from climate change, are likely to overwhelm the resilience of the DPS. We conclude that the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the Southwest Indian DPS

For the above reasons, we list the Southwest Indian DPS as a threatened species under the ESA.

North Indian DPS

We did not receive comments on the North Indian DPS, and there are no changes to our proposed listing determination. Therefore, we incorporate herein all information on the North Indian DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the North Indian DPS begins at the border of Somalia and Kenya north into the Gulf of Aden, Red Sea, Persian Gulf and east to the Gulf of Mannar off the southern tip of India and includes a major portion of India's southeastern coast up to Andra Pradesh. The southern and eastern boundaries are the equator (0°) and 84° E., respectively, which intersect in the southeast corner of the range of the DPS. It is bordered by the following countries (following the water bodies from west to east): Somalia, Djibouti, Eritrea, Sudan, Egypt, Israel, Jordan, Saudi Arabia, Yemen, Oman, United Arab Emirates, Qatar, Bahrain, Kuwait, Iraq, the Islamic Republic of Iran, Pakistan, India, and Sri Lanka.

Demographic Parameters for the North Indian DPS

The DPS exhibits high abundance, with an estimated total nester abundance of 55,243 females at 38 nesting sites. Two sites host greater than 10,000 nesting females: Ras Sharma, Yemen, and Ras Al Hadd, Oman. Nesting trends are increasing at Ras Al Hadd but possibly declining at other sites. Nesting is moderately dispersed, though concentrated in the northern and western region of the range.

Section 4(a)(1) Factors for the North Indian DPS

Nesting beaches are degraded by light pollution and uncontrolled particulate emissions that prevent the emergence of hatchlings from their nests at some beaches. Marine habitat is degraded as a result of trawling, dredging, siltation, land reclamation, and pollution. The legal and illegal harvest of turtles and eggs persists at several nesting beaches. Predation of eggs and hatchlings is a major threat at some nesting beaches. Though numerous international and national regulatory mechanisms apply to the DPS, many are inadequate due to limited implementation and enforcement. Sea turtle bycatch in gill nets, trawls, and longline fisheries is a significant cause of mortality. Vessel strikes are a large and increasing threat. Beach driving causes hatchling turtles to be caught in ruts, struck, or run over. Marine debris entangles and is ingested by turtles. Sea level rise and the increased frequency and intensity of storm events, as a result of climate change, are likely to cause severe erosion to nesting beaches.

Conservation Efforts for the North Indian DPS

There are several multinational and national programs underway to protect and conserve the DPS. Most focus on protecting the nesting beaches.

Extinction Risk Analysis for the North Indian DPS

The high abundance and broadly distributed nesting beaches of the DPS provide some resilience to threats; however, nesting is relatively concentrated and declining at some beaches. The DPS is threatened by the following factors: habitat loss and degradation, harvest of turtles and eggs, predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, beach driving, boat strikes, and climate change. While conservation efforts for the North Indian DPS are extensive and expanding, they remain inadequate to ensure the long-term viability of the population. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because resilience is limited and several of the existing threats are likely to increase. Therefore, the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the North Indian DPS

For the above reasons, we list the North Indian DPS as a threatened species under the ESA.

East Indian-West Pacific DPS

The comments that we received on the East Indian-West Pacific DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the East Indian-West Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The western boundary for the range of the East Indian-West Pacific DPS is 84° E. longitude from 40° S. to where it coincides with India near Odisha, northeast along the shoreline and into the West Pacific Ocean to include Taiwan extending east at 41° N. to 146° E. longitude, south and west to 4.5° N., 129° E., then south and east to West Papua in Indonesia and the Torres Straits in Australia. The southern boundary is 40° S. latitude, encompassing the Gulf of Carpentaria.

Demographic Parameters for the East Indian-West Pacific DPS

The DPS exhibits high abundance, with an estimated total nester abundance of 77,009 females at 50 nesting sites. The largest nesting site (Wellesley Group in northern Australia) supports approximately 25,000 nesting females. Declines occur at several nesting sites, though others appear to be stable or increasing. There is complex and significant spatial substructure, but some mixing of turtles occurs at foraging areas. Nesting and foraging areas are widespread throughout the range of the DPS, providing some resilience through habitat diversity.

Section 4(a)(1) Factors for the East Indian-West Pacific DPS

The majority of nesting beaches are degraded due to tourism, coastal development, artificial lighting, sand mining, oil and gas production, and marine debris. Foraging habitat is degraded due to siltation, sewage, pollution (*e.g.*, oil spills, agricultural runoff, and organic chemicals), commercial harvest of seagrass, trawling, dynamite and potassium cyanide fishing, and vessel anchoring. The harvest of turtles and eggs has led to declines throughout the range of the DPS. At-sea poaching is a common problem. There is rising incidence of FP. Nest and hatchling predation is prevalent. Though numerous regulatory mechanisms apply to the DPS, many are inadequately implemented and enforced. Incidental capture in artisanal and commercial fisheries (*e.g.*, those using drift and set gill nets, bottom and mid-water trawling, fishing dredges, pound nets and weirs, and haul and purse seines) is a significant and increasing threat. Turtles ingest and become entangled in marine debris, including discarded fishing gear (*e.g.*, Wilcox *et al.*, 2015). Climate change poses an increasing threat to the DPS through the loss of nesting habitat (due to sea level rise and increasing storm events) and the alteration of thermal sand characteristics of beaches (from warming temperatures).

Conservation Efforts for the East Indian-West Pacific DPS

There are several conservation programs throughout the range of the DPS. Sanctuaries and parks protect some nesting beaches, and some marine protected areas have been established. There are bycatch reduction efforts in some areas. Several programs conduct monitoring, education, outreach, and enforcement.

Extinction Risk Analysis for the East Indian-West Pacific DPS

The high nesting abundance and spatial diversity of nesting and foraging locations provide the DPS with some resilience against current threats; however, nesting trends at several sites are declining. The DPS is threatened by all section 4(a)(1) factors: Habitat loss and degradation, overexploitation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, and climate change. Though beneficial, the conservation efforts do not adequately reduce threats. We conclude that the East Indian-West Pacific DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because current and increasing threats are likely to exacerbate population declines, especially in the context of climate change. For these reasons, the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the East Indian-West Pacific DPS

For the above reasons, we list the East Indian-West Pacific DPS as a threatened species under the ESA.

Central West Pacific DPS

The comments that we received on the Central West Pacific DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the Central West Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the Central West Pacific DPS has a northern boundary of 41° N. latitude and is bounded by 41° N., 169° E. in the northeast corner, going southeast to 9° N., 175° W., then southwest to 13° S., 171° E., west and slightly north to the eastern tip of Papua New Guinea, along the northern shore of the Island of New Guinea to West Papua in Indonesia, northwest to 4.5° N., 129° E. then to West Papua in Indonesia, then north to 41° N., 146° E. It encompasses the Republic of Palau, Federated States of Micronesia, New Guinea, Solomon Islands, Marshall Islands, Guam, CNMI, and the Ogasawara Islands of Japan.

Demographic Parameters for the Central West Pacific DPS

The DPS exhibits low nesting abundance, with an estimated total nester abundance of 6,518 females at 50 nesting sites. Nesting data indicate increasing trends at one site but decreasing trends at others. There is significant genetic substructure and limited connectivity among four independent stocks. Nesting is relatively widespread but occurs only on islands and atolls (*i.e.*, little nesting site diversity).

Section 4(a)(1) Factors for the Central West Pacific DPS

Nesting habitat is degraded by coastal development and construction, placement of barriers to nesting, beachfront lighting, tourism, vehicular and pedestrian traffic, sand extraction, beach erosion, beach pollution, removal of native vegetation, and the presence of non-native vegetation. Destruction and modification of marine habitat occurs as a result of coastal construction, tourism, sedimentation, pollution, sewage, runoff, military activities, dredging, destructive fishing methods, and boat anchoring. The harvest of turtles and eggs is a large and persistent threat throughout the range of the DPS. Predation is a significant threat in some areas. Though there are some existing regulatory mechanisms to reduce the harvest of turtles and eggs and to prevent or reduce bycatch, implementation and enforcement are inadequate. Turtles are incidentally caught in longline, pole and line, and purse seine fisheries. Marine debris results in the mortality of sea turtles through ingestion and entanglement. Temperature increases, as a result of climate change, are the greatest long-term threat to atoll morphology in nations throughout the range of the DPS. Sea level rise is likely to reduce available nesting habitat. The increased frequency and intensity of storm events are likely to cause beach erosion and nest inundation, as demonstrated in a recent study by Summers *et al.* (in progress). However, Ford and Kench (2015, 2016) recently described shoreline accretion in the Marshall Islands, despite typhoon-driven erosion and local sea level rise.

Conservation Efforts Evaluation for the Central West Pacific DPS

Conservation efforts include programs to protect turtles, establish protected areas, and reduce beach pollution. A recent study demonstrates that turtle densities have increased by an order of magnitude in a marine protected area in Guam (Martin *et al.*, 2016).

Extinction Risk Analysis for the Central West Pacific DPS

The low nesting abundance, limited connectivity, and low nesting diversity provide the DPS with little resilience against current threats. Though nesting trends are increasing in some areas, they are decreasing in others. The DPS is vulnerable to the following section 4(a)(1) factors: Habitat modification and destruction, overexploitation, predation, fisheries bycatch, marine debris, and climate change. Conservation efforts do not adequately reduce such threats; ESA and additional protections are essential to the continued existence of the DPS. We conclude that the DPS is in danger of extinction throughout all or a significant portion of its range.

Listing Determination for the Central West Pacific DPS

For the above reasons, we list the Central West Pacific DPS as an endangered species under the ESA.

Southwest Pacific DPS

We did not receive comments on the Southwest Pacific DPS and made no changes to our proposed listing determination. Therefore, we incorporate herein all information on the Southwest Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the Southwest Pacific DPS extends from the western boundary of Torres Strait, to the eastern tip of Papua New Guinea and out to the offshore coordinate of 13° S., 171° E.; the eastern boundary runs from this point southeast to 40° S., 176° E.; the southern boundary runs along 40° S. from 142° E. to 176° E.; and the western boundary runs from 40° S., 142° E. north to the Australian coast then follows the coast northward to the Torres Strait.

Demographic Parameters for the Southwest Pacific DPS

The DPS exhibits high nesting abundance, with an estimated total nester abundance of 83,058 females at 12 aggregated nesting sites. Three sites (all in Australia) host more than 10,000 nesting females: Raine Island, Moulter Cay, and the Capricorn and Bunker Group. Nesting data indicate slightly increasing trends. There are four regional genetic stocks, though mixing occurs at foraging areas. Nesting and foraging areas are widely dispersed.

Section 4(a)(1) Factors for the Southwest Pacific DPS

Nesting habitat has been degraded by beach erosion, artificial lighting, pollution, removal of native vegetation, and planting of non-native vegetation. Threats to foraging habitat include destructive fishing practices, channel dredging, and marine pollution. Harvest of turtles and eggs is substantial and occurs in many areas. Several species prey on eggs and hatchlings. Existing regulatory mechanisms inadequately address the incidental take of turtles, and many are not enforced at the local level. Incidental capture in artisanal and commercial fisheries (*e.g.*, trawl, longline, drift net, and set net fisheries) is a significant threat. Vessel strikes injure or kill turtles in coastal waters. Port dredging and marine debris pose minor threats to the DPS. Climate change impacts are likely to result in increased hatchling mortality, skewed sex ratios, range shifts, diet shifts, and loss of nesting habitat.

Conservation Efforts for the Southwest Pacific DPS

Conservation efforts for the DPS have resulted in take prohibitions, implementation of bycatch reduction devices, improvement of shark control devices, and safer dredging practices. Most nesting occurs on protected beaches, and the habitat off the largest nesting site falls within a marine protected area.

Extinction Risk Analysis for the Southwest Pacific DPS

The high nesting abundance, slightly increasing trends, and spatial diversity provide the DPS with some resilience against current threats, which include: Habitat loss and degradation, overexploitation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, boat strikes, marine debris, port dredging, and climate change. Though beneficial, the conservation efforts are not sufficient to reduce all threats. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because of several continuing and increasing threats, as summarized above. As a result of such threats, we conclude that the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the Southwest Pacific DPS

For the above reasons, we list the Southwest Pacific DPS as a threatened species under the ESA.

Central South Pacific DPS

The comments that we received on the Central South Pacific DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the Central South Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the DPS extends north and east of New Zealand to include a longitudinal expanse of 7,500 km, from Easter Island, Chile in the east to Fiji in the west, and encompasses American Samoa, French Polynesia, Cook Islands, Fiji, Kiribati, Tokelau, Tonga, and Tuvalu. Its open ocean polygonal boundary endpoints are (clockwise from the northwest-most extent): 9° N., 175° W. to 9° N., 125° W. to 40° S., 96° W. to 40° S., 176° E., to 13° S., 171° E., and back to 9° N., 175° W.

Demographic Parameters for the Central South Pacific DPS

The DPS exhibits low nesting abundance, with an estimated total nester abundance of 2,677 to 3,600 nesting females at 59 nesting sites. There is a negative nesting trend at the most abundant nesting site but increasing trends at less abundant nesting beaches. There are at least two genetic stocks within the DPS. Nesting is geographically broad, but there is little diversity of nesting sites, with most nesting occurring on low-lying coral atolls or oceanic islands.

Section 4(a)(1) Factors for the Central South Pacific DPS

Some nesting beaches are degraded by coastal erosion, development, construction, sand extraction, artificial lighting, proximity to road traffic, and natural disasters, such as tsunamis. Marine habitat is degraded by runoff, sedimentation, dredging, ship groundings, natural disasters, and pollution (*e.g.*, oil spills, toxic and industrial wastes, and heavy metals). Commercial and traditional exploitation of turtles and eggs has resulted in declines at the most abundant nesting site and other locations. Illegal harvest of turtles and eggs is also a major threat.

Predation by introduced species is a significant threat in some areas. Regulatory mechanisms are inadequate to curb the continued loss and degradation of habitat and the harvest of turtles and eggs. Incidental capture in artisanal and commercial fisheries (*e.g.,* line, trap, and net fisheries) is a significant threat to the DPS. The primary gear types involved in these interactions include longlines, traps, and nets. Injury and mortality result from the entanglement in and ingestion of plastics, monofilament fishing line, and other marine debris (*e.g.,* Wedemeyer-Strombel *et al.,* 2015). Islands within the South Pacific are especially vulnerable to sea level rise, which together with increasing storm events, is likely to reduce available nesting habitat.

Conservation Efforts for the Central South Pacific DPS

Conservation efforts throughout the region, such as establishment of protected areas and national legislation to protect turtles, provide some benefits to the DPS. The remoteness of some areas appears to provide the most conservation protection against certain threats, such as poaching.

Extinction Risk Analysis for the Central South Pacific DPS

The low nesting abundance, decreasing nesting trends at the largest nesting site, and low nesting diversity provide the DPS with little resilience against current threats. Though nesting trends are increasing at some less abundant nesting beaches, such trends provide little additional resilience to the DPS. Therefore, the DPS is vulnerable to the following section 4(a)(1) factors: Habitat loss and degradation, overexploitation, predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, and climate change. Conservation efforts do not adequately reduce such threats; ESA and additional protections are essential to the continued existence of the DPS. We conclude that the DPS is in danger of extinction throughout all or a significant portion of its range.

Listing Determination for the Central South Pacific DPS

For the above reasons, we list the Central South Pacific DPS as an endangered species under the ESA.

Central North Pacific DPS

The comments that we received on the Central North Pacific DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the Central North Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the Central North Pacific DPS includes the Hawaiian Archipelago and Johnston Atoll. It is bounded by a four-sided polygon with open ocean extents reaching to 41° N., 169° E. in the northwest corner, 41° N., 143° W. in the northeast, 9° N., 125° W. in southeast, and 9° N., 175° W. in the southwest.

Demographic Parameters for the Central North Pacific DPS

The DPS exhibits low nesting abundance, with an estimated total nester abundance of 3,846 nesting females at 13 nesting sites. The most recent published study on this DPS estimates the total nester abundance at roughly 4,000 nesting females (Balazs *et al.,* 2015). The nesting trend is increasing. Nesting site diversity is extremely limited: 96 percent of nesting occurs at one low-lying atoll (*i.e.,* FFS).

Section 4(a)(1) Factors for the Central North Pacific DPS

In the MHI, nesting and basking habitats are degraded by coastal development and construction, vehicular and pedestrian traffic, beach pollution, tourism, and other human related activities. Foraging habitat is degraded by coastal development, marina construction, siltation, pollution, sewage, military activities, vessel traffic, and vessel groundings. As stated in a recent study, FP continues to cause the majority of green turtle strandings in Hawaiʻi (Work *et al.,* 2015) and may be linked to environmental factors (Keller *et al.,* 2014; Van Houtan *et al.,* 2014; Work *et al.,* 2014; NMFS, in progress). Numerous native and non-native predators prey on hatchlings and eggs. Existing regulatory mechanisms do not adequately address the threat of bycatch in international fisheries. In addition to incidental capture in foreign longline fisheries, interactions with nearshore recreational fisheries occur (Work *et al.,* 2015). Marine debris is a significant threat (*e.g.,* Wedemeyer-Strombel *et al.,* 2015); entanglement in lost or discarded fishing gear is the second leading cause of strandings and mortality in the MHI (Work *et al.,* 2015). Vessel strikes result in injury and mortality. Vessel traffic excludes turtles from their preferred foraging areas. The extremely limited nesting diversity (*i.e.,* 96 percent of nesting at FFS) increases extinction risk by rendering the DPS vulnerable to random variation and environmental stochasticities. In addition, climate change impacts threaten the DPS. Sea level rise and the increasing frequency and intensity of storm events are likely to reduce available nesting habitat. A recent study indicated that increasing temperatures are likely to modify beach thermal regimes that are important to nesting and basking (Van Houtan *et al.,* 2015). Temperature increases are also likely to result in increased hatchling mortality, skewed sex ratios, and changes in juvenile and adult distribution patterns.

Conservation Efforts for the Central North Pacific DPS

Overall, State and Federal conservation efforts have been successful in countering some threats. Important State initiatives include the regulation of gill net fishing and the distribution of barbless circle hooks.

Extinction Risk Analysis for the Central North Pacific DPS

Though the low nesting abundance and extremely limited nesting diversity render the DPS vulnerable to several threats, the increasing nesting trend at FFS provides some resilience. The DPS is threatened by the following section 4(a)(1) factors: Present and threatened habitat loss and degradation, disease and predation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, vessel activities, limited spatial diversity, and climate change. Though beneficial, the conservation efforts are not sufficient to reduce all threats. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because of numerous continuing and increasing threats, which would be further exacerbated if ESA protections were lost. We conclude that the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the Central North Pacific DPS

For the above reasons, we list the Central North Pacific DPS as a threatened species under the ESA.

East Pacific DPS

The comments that we received on the East Pacific DPS did not change our conclusions regarding its listing determination. Therefore, we incorporate herein all information on the East Pacific DPS provided in the Status Review Report and proposed rule, with the exception of the application of the critical risk threshold from the Status Review Report, which does not directly correlate with the ESA definitions of "endangered" and "threatened," as explained in the proposed rule. The following represents a brief summary of that information.

The range of the DPS extends from 41° N. southward along the Pacific coast of the Americas to central Chile (40° S.) and westward to 142° W. and 96° W., respectively. The offshore boundary of this DPS is a straight line between these two coordinates. The East Pacific DPS includes the Mexican Pacific coast breeding population, which was originally listed as endangered (43 FR 32800, July 28, 1978).

Demographic Parameters for the East Pacific DPS

The DPS exhibits an estimated total nester abundance of 20,112 females at 39 nesting sites. The largest nesting aggregation (Colola, Michoacán, Mexico) hosts more than 10,000 nesting females. Nesting data indicate increasing trends in recent decades. Within the DPS, there is additional substructure, and four regional genetic stocks have been identified; however, stocks mix at foraging areas. Nesting occurs at both insular and continental sites, providing some spatial diversity.

Section 4(a)(1) Factors for the East Pacific DPS

Some nesting beaches are degraded by coastal development, tourism, and pedestrian traffic. Some foraging areas exhibit high levels of contaminants and reduced seagrass communities. As described by Senko *et al.* (2014), the direct harvest of turtles is a significant source of mortality. The legal and illegal harvest of eggs is a significant threat due to high demand and lack of enforcement of existing protections. Predation by dogs results in egg and hatchling mortality (Ruiz-Izaguirre *et al.*, 2015; Santidrián Tomillo *et al.*, 2015). Existing regulatory mechanisms inadequately regulate egg poaching, the destruction of nesting habitat, and fisheries bycatch. Incidental capture in artisanal and commercial fisheries (*e.g.*, longline, drift gill net, set gill net, and trawl fisheries) is a significant threat. Other threats include marine debris ingestion, boat strikes, and red tide poisoning, which may result in a UME. Climate change is likely to impact nesting and hatchling success. In a recent study, Rhodes (2015) found that females laid fewer nests in areas characterized by erosion and tidal inundation (two likely impacts of sea level rise).

Conservation Efforts for the East Pacific DPS

Conservation initiatives include broad regional efforts and national programs, such as the National Programme for the Conservation of Marine and Continental Turtles in Colombia, which provides education, conservation, and outreach plans. Marine reserves protect green turtles and their foraging habitat.

Extinction Risk Analysis for the East Pacific DPS

The increasing trends and spatial diversity provide the DPS with some resilience against current threats; the nesting abundance, though not high, may be large enough to avoid depensation and other risks associated with small population size. The DPS is threatened by the following section 4(a)(1) factors: Habitat loss and degradation, overexploitation, inadequate regulatory mechanisms, fisheries bycatch, marine debris, boat strikes, red tide poisoning, and climate change. Though beneficial, conservation efforts are not sufficient to adequately reduce threats. We conclude that the DPS is not presently in danger of extinction throughout all or a significant portion of its range. Listing is warranted because significant threats (*e.g.*, egg poaching) continue and others (*e.g.*, climate change) are increasing. The loss of ESA protections would further exacerbate several threats. We conclude that the DPS is likely to become endangered within the foreseeable future throughout all or a significant portion of its range.

Listing Determination for the East Pacific DPS

For the above reasons, we list the East Pacific DPS as a threatened species under the ESA.

Final Determination

We reviewed the best available scientific and commercial information, including the information in the Status Review Report, the comments of peer reviewers, public comments, and information that has become available since the publication of the proposed rule. We identified 11 green turtle DPSs: North Atlantic, Mediterranean, South Atlantic, Southwest Indian, North Indian, East Indian-West Pacific, Central West Pacific, Southwest Pacific, Central South Pacific, Central North Pacific, and East Pacific. For each DPS, we reviewed the demographic parameters and section 4(a)(1) factors, performed an extinction risk analysis, and considered conservation efforts. We determined that the Mediterranean, Central West Pacific, and Central South Pacific DPSs are endangered species, and the following DPSs are threatened species: North Atlantic, South Atlantic, Southwest Indian, North Indian, East Indian-West Pacific, Southwest Pacific, Central North Pacific, and East Pacific. We hereby replace the original listings for the species and breeding populations in Florida and the Pacific coast of Mexico with listings of the 11 threatened or endangered DPSs.

Significant Portion of the Range

Under the ESA and our implementing regulations, a species may warrant listing if it is endangered or threatened throughout all or a significant portion of its range. See the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37577, July 1, 2014). Under that policy, we only need to consider whether listing may be appropriate on the basis of the "significant portion of its range" language if the rangewide analysis does not lead to a threatened or endangered listing determination. Because we have determined that each green turtle DPS is either threatened or endangered throughout all of its range, no portion of its range can be "significant" for purposes of the definitions of "endangered species" and "threatened species."

Effects of Listing

Conservation benefits for species listed as endangered or threatened under the ESA include: Recovery plans and actions (16 U.S.C. 1533(f)); designation of critical habitat if prudent and determinable (16 U.S.C. 1533(a)(3)(A)(i)); the requirement that Federal agencies consult with the Services to ensure that their actions are not likely to jeopardize species or result in adverse modification or destruction of critical habitat, should it be designated (16 U.S.C. 1536(a)(2)); and prohibitions against take and certain other activities (16 U.S.C. 1538). In addition, recognition of the species' status through listing promotes conservation actions by Federal and State agencies, foreign entities, conservation organizations, and individuals.

Identifying Section 7(a)(2) Consultation Requirements

Section 7(a)(2) of the ESA requires Federal agencies to consult with the relevant Service(s) to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat (16 U.S.C. 1536(a)(2)). The ESA requires consultation for any Federal action that may affect green turtles, which have been listed under the ESA since 1978. This will not change with the listing of the DPSs (*i.e.*, consultation is required for any Federal action that may affect any of the green turtle DPSs). Reinitiation of consultation is required for any action that may affect one or more newly listed DPS. Federal agencies must insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any green turtle DPS. Examples of Federally authorized, funded, or implemented actions that affect green turtles include, but are not limited to: Dredging and channelization, beach nourishment and nearshore construction, pile-driving, water quality standards, oil and gas exploration and extraction, power plant operations, vessel activities, military activities, and fisheries management practices.

Critical Habitat

Section 3 of the ESA defines critical habitat as: (1) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance [with the ESA], on which are found those physical or biological features (a) essential to the conservation of the species and (b) that may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by a species at the time it is listed in accordance [with the ESA] upon a determination by the Services that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)). Section 4(a)(3)(A) requires us to designate critical habitat to the maximum extent prudent and determinable and concurrently with a listing determination (16 U.S.C. 1533(a)(3)(A)(i)), unless as described in section 4(b)(6)(C), critical habitat is not then determinable, in which case we may take an additional year to publish the final critical habitat determination (16 U.S.C. 1533(b)(6)(C)(ii)). The implementing regulations state that critical habitat shall not be designated within foreign countries or in other areas outside of U.S. jurisdiction (50 CFR 424.12 (h)). The ranges of six DPSs occur within U.S. jurisdiction: North Atlantic, South Atlantic, East Pacific, Central North Pacific, Central South Pacific, and Central West Pacific. We are currently evaluating the areas that contain physical and biological features that are essential to the DPSs and may require special management considerations or protection, but critical habitat is not determinable at this time. Therefore, we will propose critical habitat in a future rulemaking. As discussed in the proposed rule, designated critical habitat, in waters surrounding Culebra Island, Puerto Rico, from the mean high water line seaward to 3 nautical miles (5.6 km; 63 FR 46693, September 2, 1998), remains in effect for the North Atlantic DPS.

Take Prohibitions

All prohibitions in section 9(a)(1) of the ESA (16 U.S.C. 1538(a)(1)) apply automatically under the statute to the three endangered DPSs: Mediterranean, Central West Pacific and Central South Pacific. These include prohibitions against importing, exporting, engaging in foreign or interstate commerce, or "taking" of the species. "Take" is defined under the ESA as "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct" (16 U.S.C. 1532(19)). These prohibitions apply to any "person" (as defined by the ESA) subject to the jurisdiction of the United States, including within the United States, its territorial seas, or on the high seas. Certain exceptions apply to employees of the Services, other Federal land management agencies, and State conservation agencies. In addition, longstanding requirements for fishing activities to protect endangered sea turtles apply to these DPSs (50 CFR 224.104) and are not affected by this rule.

Section 4(d) of the ESA authorizes us to issue regulations that we deem necessary and advisable to provide for the conservation of threatened species (16 U.S.C. 1533(d)). As discussed in the proposed rule, the longstanding protective regulations (50 CFR 17.42(b), 223.205, 223.206, and 223.207) remain in effect and continue to apply section 9 prohibitions to threatened species of sea turtles, which include the North Atlantic, South Atlantic, Southwest Indian, North Indian, East Indian-West Pacific, Southwest Pacific, Central North Pacific, and East Pacific DPSs. The specific content of those provisions is beyond the scope of this rulemaking and is unaffected by this rulemaking.

Pursuant to section 10 of the ESA, we may issue permits to carry out activities otherwise prohibited by section 9 for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities (16 U.S.C. 1539(a)(1)). For threatened species, we may also issue permits for education and zoological exhibition (50 CFR 17.32(a)(1); 50 CFR 223.206(a)(1)).

Identification of Those Activities That Would Likely Constitute a Violation of Section 9 of the ESA

On July 1, 1994, we published a policy (59 FR 34272) that requires us to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not likely constitute a violation of section 9 of the ESA. The intent of this policy is to increase public awareness of the effect of a listing on proposed and ongoing activities within a species' range. Activities likely to violate section 9 include, but are not limited to: (1) Importation or exportation of any part of a green turtle or green turtle eggs; (2) directed take of green turtles, including fishing for, capturing, handling, or possessing green turtles, eggs, or parts; (3) sale of green turtles, eggs, or parts in interstate commerce; (4) modification or degradation of green turtle habitat, including nesting beaches, beaches used for basking, and developmental, foraging habitat, and migratory habitat that actually kills or injures green turtles (*i.e.*, harm, 50 CFR 222.102); and (5) indirect take of green turtles in the course of otherwise lawful activities, such as fishing, dredging, beach nourishment, coastal construction, vessel traffic, and discharge of pollutants. Whether a particular activity violates section 9 depends upon the facts and circumstances of each incident. Because the green turtle has been listed under the ESA since 1978, we do not anticipate changes in the activities that would constitute a violation of section 9. Possible exceptions include those actions affecting the Mediterranean, Central West Pacific, and Central South Pacific DPSs, which are now listed as endangered, and the breeding populations in Florida and the Pacific coast of Mexico, which were heretofore listed as endangered. For example, the Services may issue permits for the educational use and zoological exhibition of threatened, but not endangered, sea turtles (50 CFR 17.32(a)(1); 50 CFR 223.206(a)(1)).

Activities not likely to violate section 9 of the ESA may include: Take authorized by and carried out in accordance with the terms and conditions of an ESA section 10(a)(1)(A) permit; and continued possession of parts that were in possession at the time of the original listing (*i.e.*, 1978).

Peer Review

In December 2004, the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for

Peer Review, establishing minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation. The OMB Bulletin, implemented under the Information Quality Act (Pub. L. 106–554), is intended to enhance the quality and credibility of the Federal government's scientific information and applies to influential or highly influential scientific information disseminated on or after June 16, 2005. To satisfy our requirements under the OMB Bulletin, we obtained independent peer review of the Status Review Report by 15 independent scientists with expertise in green turtle biology and genetics, endangered species listing policy, and related fields. All peer reviewer comments were addressed prior to the publication of the Status Review Report and proposed rule.

References

A complete list of the references is available at: *http://www.nmfs.noaa.gov/pr/species/turtles/green.htm.*

Classification

National Environmental Policy Act

The 1982 amendments to section 4(b)(1)(A) of the ESA restrict the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus,* 657 F. 2d 829 (6th Cir. 1981), NMFS has concluded that ESA listing actions are not subject to the requirements of the National Environmental Policy Act. See NOAA Administrative Order 216–6. Similarly, USFWS has determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act, need not be prepared in connection with regulations pursuant to section 4(a) of the ESA (48 FR 49244, October 25, 1983).

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the listing process. In addition, this final rule is exempt from review under Executive Order 12866. This final rule does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13132, Federalism

In accordance with Executive Order 13132, we determined that this final rule does not have significant Federalism effects and that a Federalism assessment is not required.

List of Subjects

50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

50 CFR Parts 223 and 224

Endangered and threatened species, Exports, Imports, Transportation.

Dated: March 29, 2016.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

Dated: March 15, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

For the reasons set out in the preamble, 50 CFR parts 17, 223, and 224 are amended as follows:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11(h), under REPTILES, remove both entries for "Sea turtle, green" and add in their place the eleven entries for "Sea turtle, green" set forth below:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*
REPTILES							
*	*	*	*	*	*		*
Sea turtle, green (Central North Pacific DPS).	*Chelonia mydas*	Central North Pacific Ocean.	Green sea turtles originating from the Central North Pacific Ocean, bounded by the following coordinates: 41° N., 169° E. in the northwest; 41° N., 143° W. in the northeast; 9° N., 125° W. in the southeast; and 9° N., 175° W. in the southwest.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Sea turtle, green (Central South Pacific DPS).	*Chelonia mydas*	Central South Pacific Ocean.	Green sea turtles originating from the Central South Pacific Ocean, bounded by the following coordinates: 9° N., 175° W. in the northwest; 9° N., 125° W. in the northeast; 40° S., 96° W. in the southeast; 40° S., 176° E. in the southwest; and 13° S., 171° E. in the west.	E	863	NA	224.104.
Sea turtle, green (Central West Pacific DPS).	*Chelonia mydas*	Central West Pacific Ocean.	Green sea turtles originating from the Central West Pacific Ocean, bounded by the following coordinates: 41° N., 146° E. in the northwest; 41° N., 169° E. in the northeast; 9° N., 175° W. in the east; 13° S., 171° E. in the southeast; along the northern coast of the island of New Guinea; and 4.5° N., 129° E. in the west.	E	863	NA	224.104.
Sea turtle, green (East Indian-West Pacific DPS).	*Chelonia mydas*	Eastern Indian and Western Pacific Oceans.	Green sea turtles originating from the Eastern Indian and Western Pacific Oceans, bounded by the following lines and coordinates: 41° N. Lat. in the north, 41° N., 146° E. in the northeast; 4.5° N., 129° E. in the southeast; along the southern coast of the island of New Guinea; along the western coast of Australia (west of 142° E. Long.); 40° S. Lat. in the south; and 84° E. Long. in the east.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (East Pacific DPS).	*Chelonia mydas*	East Pacific Ocean.	Green sea turtles originating from the East Pacific Ocean, bounded by the following lines and coordinates: 41° N., 143° W. in the northwest; 41° N. Lat. in the north; along the western coasts of the Americas; 40° S. Lat. in the south; and 40° S., 96° W. in the southwest.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (Mediterranean DPS).	*Chelonia mydas*	Mediterranean Sea.	Green sea turtles originating from the Mediterranean Sea, bounded by 5.5° W. Long. in the west.	E	863	NA	224.104.

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Sea turtle, green (North Atlantic DPS).	*Chelonia mydas*	North Atlantic Ocean.	Green sea turtles originating from the North Atlantic Ocean, bounded by the following lines and coordinates: 48° N. Lat. in the north, along the western coasts of Europe and Africa (west of 5.5° W. Long.); north of 19° N. Lat. in the east; bounded by 19° N., 65.1° W. to 14° N., 65.1° W. then 14° N., 77° W. in the south and west; and along the eastern coasts of the Americas (north of 7.5° N., 77° W.).	T	863	226.208	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (North Indian DPS).	*Chelonia mydas*	North Indian Ocean.	Green sea turtles originating from the North Indian Ocean, bounded by: Africa and Asia in the west and north; 84° E. Long. in the east; and the equator in the south.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (South Atlantic DPS).	*Chelonia mydas*	South Atlantic Ocean.	Green sea turtles originating from the South Atlantic Ocean, bounded by the following lines and coordinates: along the northern and eastern coasts of South America (east of 7.5° N., 77° W.); 14° N., 77° W. to 14° N., 65.1° W. to 19° N., 65.1° W. in the north and west; 19° N. Lat. in the northeast; 40° S., 19° E. in the southeast; and 40° S. Lat. in the south.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (Southwest Indian DPS).	*Chelonia mydas*	Southwest Indian Ocean.	Green sea turtles originating from the Southwest Indian Ocean, bounded by the following lines: the equator to the north; 84° E. Long. to the east; 40° S. Lat. to the south; and 19° E. Long (and along the eastern coast of Africa) in the west.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
Sea turtle, green (Southwest Pacific DPS).	*Chelonia mydas*	Southwest Pacific Ocean.	Green sea turtles originating from the Southwest Pacific Ocean, bounded by the following lines and coordinates: along the southern coast of the island of New Guinea and the Torres Strait (east of 142° E Long.); 13° S., 171° E. in the northeast; 40° S., 176° E. in the southeast; and 40° S., 142° E. in the southwest.	T	863	NA	17.42(b), 223.205, 223.206, 223.207.
*	*	*	*	*	*	*	*

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 3. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.*; 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 4. Amend the table in § 223.102(e) by removing the entry for "Sea turtle, green" and adding in its place the eight entries for "Sea turtle, green" under Reptiles to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
		Reptiles [2]			
Sea turtle, green (Central North Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the Central North Pacific Ocean, bounded by the following coordinates: 41° N., 169° E. in the northwest; 41° N., 143° W. in the northeast; 9° N., 125° W. in the southeast; and 9° N., 175° W. in the southwest.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
Sea turtle, green (East Indian-West Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the Eastern Indian and Western Pacific Oceans, bounded by the following lines and coordinates: 41° N. Lat. in the north, 41° N., 146° E. in the northeast; 4.5° N., 129° E. in the southeast; along the southern coast of the island of New Guinea; along the western coast of Australia (west of 142° E. Long.); 40° S. Lat. in the south; and 84° E. Long. in the east.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
Sea turtle, green (East Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the East Pacific Ocean, bounded by the following lines and coordinates: 41° N., 143° W. in the northwest; 41° N. Lat. in the north; along the western coasts of the Americas; 40° S. Lat. in the south; and 40° S., 96° W. in the southwest.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
Sea turtle, green (North Atlantic DPS).	*Chelonia mydas*	Green sea turtles originating from the North Atlantic Ocean, bounded by the following lines and coordinates: 48° N. Lat. in the north, along the western coasts of Europe and Africa (west of 5.5° W. Long.); north of 19° N. Lat. in the east; bounded by 19° N., 65.1° W. to 14° N., 65.1° W. then 14° N., 77° W. in the south and west; and along the eastern coasts of the Americas (north of 7.5° N., 77° W.).	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	226.208	223.205, 223.206, 223.207.
Sea turtle, green (North Indian DPS).	*Chelonia mydas*	Green sea turtles originating from the North Indian Ocean, bounded by: Africa and Asia in the west and north; 84° E. Long. in the east; and the equator in the south.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
Sea turtle, green (South Atlantic DPS).	*Chelonia mydas*	Green sea turtles originating from the South Atlantic Ocean, bounded by the following lines and coordinates: Along the northern and eastern coasts of South America (east of 7.5° N., 77° W.); 14° N., 77° W. to 14° N., 65.1° W. to 19° N., 65.1° W. in the north and west; 19° N. Lat. in the northeast; 40° S., 19° E. in the southeast; and 40° S. Lat. in the south.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.

Species[1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
Sea turtle, green (Southwest Indian DPS).	*Chelonia mydas*	Green sea turtles originating from the Southwest Indian Ocean, bounded by the following lines: The equator to the north; 84° E. Long. to the east; 40° S. Lat. to the south; and 19° E. Long (and along the eastern coast of Africa) in the west.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
Sea turtle, green (Southwest Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the Southwest Pacific Ocean, bounded by the following lines and coordinates: Along the southern coast of the island of New Guinea and the Torres Strait (east of 142° E Long.); 13° S., 171° E. in the northeast; 40° S., 176° E. in the southeast; and 40° S., 142° E. in the southwest.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	223.205, 223.206, 223.207.
*	*	*	*	*	*

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[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

[2] Jurisdiction for sea turtles by the Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service, is limited to turtles while in the water.

PART 224—ENDANGERED MARINE AND ANADROMOUS SPECIES

■ 5. The authority citation for part 224 continues to read as follows:

Authority: 16 U.S.C. 1531–1543 and 16 U.S.C. 1361 *et seq.*

■ 6. Amend § 224.101(h) by removing the entry for "Sea turtle, green" and adding in its place the three entries for "Sea turtle, green" under Reptiles to read as follows:

§ 224.101 Enumeration of endangered marine and anadromous species.

* * * * *

(h) * * *

Species[1]			Citation(s) for listing determination(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
*	*	*	*	*	*
		Reptiles[2]			
Sea turtle, green (Central South Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the Central South Pacific Ocean, bounded by the following coordinates: 9° N., 175° W. in the northwest; 9° N., 125° W. in the northeast; 40° S., 96° W. in the southeast; 40° S., 176° E. in the southwest; and 13° S., 171° E. in the west.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	224.104.
Sea turtle, green (Central West Pacific DPS).	*Chelonia mydas*	Green sea turtles originating from the Central West Pacific Ocean, bounded by the following coordinates: 41° N., 146° E. in the northwest; 41° N., 169° E. in the northeast; 9° N., 175° W. in the east; 13° S., 171° E. in the southeast; along the northern coast of the island of New Guinea; and 4.5° N., 129° E. in the west.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	224.104.
Sea turtle, green (Mediterranean DPS).	*Chelonia mydas*	Green sea turtles originating from the Mediterranean Sea, bounded by 5.5° W. Long. in the west.	81 FR [Insert **Federal Register** page where the document begins], 4/6/16.	NA	224.104.
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[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

[2] Jurisdiction for sea turtles by the Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service, is limited to turtles while in the water.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 1 and 11
Sanitary Transportation of Human and Animal Food; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 11

[Docket No. FDA–2013–N–0013]

RIN 0910–AG98

Sanitary Transportation of Human and Animal Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to establish requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. This action is part of our larger effort to focus on prevention of food safety problems throughout the food chain and is part of our implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA) and the Food Safety Modernization Act of 2011 (FSMA).

DATES: This rule is effective June 6, 2016. See section V for the compliance dates.

FOR FURTHER INFORMATION CONTACT: Michael Kashtock, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2022.

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Executive Summary

Purpose and Coverage of the Rule

This rule is part of FDA's implementation of the 2005 SFTA and the FSMA. These statutes require us to issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. This rule creates new requirements for the sanitary transportation of human and animal food by motor vehicle and rail vehicle to ensure that transportation practices do not create food safety risks. Practices that create such risk include failure to properly refrigerate food requiring temperature control for food safety, the inadequate cleaning of vehicles between loads, and the failure to otherwise properly protect food during transportation. This rule builds on current safe food transportation best practices and is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. The rule is flexible to allow the transportation industry to continue to use industry best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment to ensure that food is transported under the conditions and controls necessary to prevent adulteration linked to food safety.

Summary of the Major Provisions of the Rule

As required by the 2005 SFTA, this final rule addresses the sanitary transportation of food (human and animal food) by establishing criteria and definitions that apply in determining whether food is adulterated because it has been transported or offered for transport by a shipper, loader, carrier by motor vehicle or rail vehicle, or receiver engaged in the transportation of food under conditions that are not in compliance with the sanitary food transportation regulations. This rule defines transportation as "any movement of food in commerce by motor vehicle or rail vehicle" and establishes requirements for sanitary transportation practices applicable to shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in food transportation operations addressing:

- Vehicles and transportation equipment;
- Transportation operations;
- Training;
- Records; and
- Waivers.

This rule allows the transportation industry to continue to use best practices, *i.e.*, "commercial or professional procedures that are accepted or prescribed as being correct or most effective," (Ref. 1), concerning cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent adulteration linked to food safety.

We made several revisions to this final rule, in response to comments that we received regarding the proposed rule, to affirm that the use of current sanitary food transportation best practices as described in these comments, *e.g.*, the "Rendering Industry Code of Practice" and "Model Tanker Wash Guidelines For the Fruit Juice Industry," will allow industry to meet the requirements of this rule. Some of these best practices have been provided to the Agency as industry documents submitted with comments on the proposed rule, while others were described in the comments or the public meetings we held for the proposed rule.

As discussed in detail in later sections of the rule, we made several major revisions to the provisions of this rule mainly in response to comments that focus the rule more narrowly on food safety and are consistent with existing safe transportation best practices. These major revisions include the following:

- We have simplified the definitions for parties covered by the rule to make them all activity based and added a definition for "loader" as a new party covered by the rule, based on comments indicating that this was a relevant segment of the transportation industry that we had not previously identified.
- We have amended the definition of "transportation operations" such that additional transportation activities are not covered by the rule, including transport of food completely enclosed by a container, except food that requires temperature control for safety (broadens proposed exclusion for transport of shelf stable food completely enclosed by a container), food contact substances, and human food byproducts transported for use as animal food without further processing.
- We changed the provisions of the rule to focus on food safety concerns and not additionally adulteration as a result of spoilage or quality defects. Therefore, we have replaced language indicating that the goal of the rule is prevention of both food safety and non-safety concerns with language indicating that the goal is prevention of food becoming "unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act" during transportation operations.
- We have removed prescriptive requirements for temperature monitoring devices and continuous monitoring of temperature during transport and replaced these provisions with a more flexible approach which allows the shipper and carrier to agree to a temperature monitoring mechanism for shipments of food that require temperature control for safety. We have also removed the provision requiring the carrier to demonstrate temperature control to the receiver for every shipment requiring temperature control. In this final rule, the demonstration must only be made if the shipper or receiver requests it, which is consistent with industry best practices and would likely only be done in situations in which it is suspected that there has been a material failure of temperature control.
- We have revised this rule to require that if a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the person must take appropriate action, to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual, that the temperature deviation or other condition did not render the food unsafe.
- We have revised the requirements of this final rule to make it clear that its requirements account for the fact that the intended use of the vehicle or equipment with respect to the type of food that is being transported, *e.g.,* the transportation of animal feed versus food for humans, is relevant in establishing the applicable sanitary transportation requirements, as is the production stage of the food being transported, *e.g.,* raw materials, ingredients, or finished food products.
- Finally, we have revised the rule to primarily place the responsibility for determinations about appropriate transportation operations (*e.g.,* whether food needs temperature control for safety and the relevant operating temperature and mode of temperature monitoring, whether particular clean out procedures are needed, and whether previous cargo must be identified) on the shipper. The shipper may rely on contractual agreements to assign some of these responsibilities to other parties, such as a loader or carrier, if they agree to accept the responsibility. We believe the shipper is in the best position of the parties covered by this rule to know the appropriate specifications for transport of its food.

Costs and Benefits

This final rule implements requirements addressing the sanitary transportation of human and animal food. It establishes requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, loaders, and receivers. Specifically, these finalized requirements address design and maintenance of vehicles and transportation equipment; sanitary practices during transportation operations that apply to shippers, receivers, loaders, and carriers; training of carrier employees; and records related to, for example, training, and written procedures. As shown in table 1, the total annualized costs are estimated to be approximately $113 million per year, estimated with a 3 percent discount rate, and $117 million per year, estimated at 7 percent when discounted over 10 years. We do not have sufficient data to fully quantify the benefits of this regulation.

TABLE 1—ESTIMATED COSTS AND BENEFITS

[In millions of $]

	Initial costs	Annual	Benefits
	$162.7	$93.5	Not quantified.

Costs Annualized over 10 Years

	Costs	Benefits
3%	$113	Not quantified.
7%	117	

I. Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111–353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities and international collaborations with foreign regulatory counterparts. A top priority for FDA are those FSMA-required regulations that provide the framework for industry's implementation of preventive controls and enhance our ability to oversee their implementation for both domestic and imported food. To that end, we proposed the seven foundational rules listed in table 2 and requested comments on all aspects of these proposed rules.

TABLE 2—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2013 proposed human preventive controls regulation.	78 FR 3646, January 16, 2013.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2013 proposed produce safety regulation.	78 FR 3504, January 16, 2013.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2013 proposed animal preventive controls regulation.	78 FR 64736, October 29, 2013.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2013 proposed FSVP regulation	78 FR 45730, July 29, 2013.
Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications.	2013 proposed third-party certification regulation.	78 FR 45782, July 29, 2013.
Focused Mitigation Strategies To Protect Food Against Intentional Adulteration.	2013 proposed intentional adulteration regulation.	78 FR 78014, December 24, 2013.
Sanitary Transportation of Human and Animal Food	2014 proposed sanitary transportation regulation.	79 FR 7006, February 5, 2014.

We also issued a supplemental notice of proposed rulemaking for the rules listed in table 3 and requested comments on specific issues identified in each supplemental notice of proposed rulemaking.

TABLE 3—PUBLISHED SUPPLEMENTAL NOTICES OF PROPOSED RULEMAKING FOR THE FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food.	2014 supplemental human preventive controls notice.	79 FR 58524, September 29, 2014.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	2014 supplemental produce safety notice.	79 FR 58434, September 29, 2014.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.	2014 supplemental animal preventive controls notice.	79 FR 58476, September 29, 2014.
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals.	2014 supplemental FSVP notice	79 FR 58574, September 29, 2014.

We finalized five of the foundational rulemakings listed in table 4 in September and November 2015.

TABLE 4—PUBLISHED FOUNDATIONAL RULES FOR IMPLEMENTATION OF FSMA

Title	Abbreviation	Publication
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.	Final human preventive controls regulation.	80 FR 55908, September 17, 2015.
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.	Final animal preventive controls regulation.	80 FR 56170, September 17, 2015.
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.	Final FSVP regulation	80 FR 74225, November 27, 2015.
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	Final produce safety regulation	80 FR 74353, November 27, 2015.
Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications.	N/A	80 FR 74569, November 27, 2015.

As FDA finalizes these seven foundational rulemakings, we are putting in place a modern, risk-based framework for food safety, based on the most recent science, that focuses efforts where the hazards are reasonably likely to occur, and that is flexible and practical given our current knowledge of food safety practices. To achieve this, FDA has engaged in a significant amount of outreach to the stakeholder community to find the right balance between flexibility and accountability in these regulations.

After FSMA was enacted in 2011, we have been involved in approximately 600 stakeholder engagements on FSMA and the proposed rules, including public meetings, Webinars, listening sessions, farm tours, and extensive presentations and meetings with various stakeholder groups (Refs. 2 and 3). As a result of this stakeholder dialogue, FDA decided to issue the four supplemental notices of proposed rulemaking to share our current thinking on key issues and get additional stakeholder input on those issues. As we move forward into the next phase of FSMA implementation, we intend to continue this dialogue and collaboration with our stakeholders, through guidance, education, training, and assistance, to ensure that stakeholders understand and engage in their respective roles in food safety. FDA believes these seven foundational final rules, when implemented, will affect the paradigm shift toward prevention that was envisioned in FSMA and be a major step forward for food safety that will help protect consumers into the future.

B. What risks to humans and animals have been associated with the transportation of food? How has this issue been addressed in the past?

Due to illness outbreaks involving human food and animal food that became contaminated during transportation (Refs. 4 and 5), and incidents and reports of insanitary transportation practices (Refs. 6 to 11), there have been concerns over the past few decades about the need to ensure that food is transported in the United States in a sanitary manner (Ref. 12). Press accounts in the late 1980s of trucks carrying food from the Midwest to both the East and West Coasts and returning with garbage for Midwest landfills caused concern that food products could become contaminated and unfit for human consumption if irresponsible vehicle operators failed to properly clean vehicles that had been previously used to haul waste or other nonfood materials (Refs. 13 to 15). Congress responded to these concerns by passing the Sanitary Food Transportation Act of 1990 (1990 SFTA) (Pub. L. 101–500), which directed the Department of Transportation (DOT) to establish regulations to prevent food or food additives transported in certain types of bulk vehicles from being contaminated by nonfood products that were simultaneously or previously transported in those vehicles. Following the passage of the 1990 SFTA it became clear that potential sources of food contamination during transport were not just limited to nonfood products. Most notably, a 1994 outbreak of salmonellosis occurred in which ice cream mix became contaminated during transport in tanker trucks that had previously hauled raw liquid eggs. That outbreak affected an estimated 224,000 persons nationwide (Ref. 4). In 2005, Congress reallocated authority for food transportation safety to FDA, DOT, and USDA by passing the 2005 SFTA, a broader food transportation safety law than the 1990 SFTA. The focus of the 2005 SFTA was not limited only to preventing food contamination from nonfood sources during transportation.

C. What did the Sanitary Food Transportation Act of 2005 and the Food Safety Modernization Act of 2011 do with respect to food transportation? What other activities did we conduct for this rulemaking?

The 2005 SFTA directed us to establish regulations prescribing sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food. Section 111(a) of FSMA also directed FDA to issue these sanitary transportation regulations. In April of 2010, we issued guidance to provide the industry with broadly applicable recommendations for controls to prevent food safety problems during transport while we worked toward implementing the 2005 SFTA (Ref. 16). We also published a **Federal Register** advance notice of proposed rulemaking in 2010 (the 2010 ANPRM; 75 FR 22713, April 30, 2010) to request data and information on the food transportation industry and its practices to prevent the contamination of transported foods and any associated outbreaks.

D. What did we propose to do?

We subsequently published a proposed rule in the **Federal Register** of February 5, 2014 (79 FR 7006), to establish sanitary transportation requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of both human and animal food to ensure the safety of the food they transport.

In brief, we proposed to address the sanitary transportation of food for humans and animals by establishing definitions and criteria that would apply to determine whether food is adulterated because it has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, or receiver under conditions that are not in compliance with the sanitary food transportation regulations. We proposed to define transportation as any movement of food in commerce by motor vehicle or rail vehicle. We proposed to establish requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in food transportation operations. Specifically, we proposed to establish requirements for:

- Vehicles and transportation equipment;
- Transportation operations;
- Training;
- Records; and
- Waivers.

The proposed rule would allow the transportation industry to continue to use best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

We received about 240 submissions in response to the proposed rule. We received comments from individuals, industry and trade associations, consumer and advocacy groups, academia, law firms, professional organizations, Federal and State, tribal and foreign government agencies and other organizations. In this document, we describe these comments, respond to them, and explain any revisions we made to the proposed rule in response to those comments. In addition, we held three public meetings to discuss the proposed rule. The meetings took place on February 27, 2014, in Chicago, IL; March 13, 2014, in Anaheim, CA; and March 20, 2014, in Washington, DC.

Some comments address issues that are outside the scope of this rule. For example, a comment suggests that we undertake a comprehensive examination of transportation that occurs by ship or barge within, into, or out of the United States to provide Congress with sufficient information to reevaluate our safe food transportation statutory authority (see responses to Comment 9 and Comment 30). Another comment states that this rule should identify the parties who are responsible for paying attorney's fees in cases where claims are made for damage that occurs during truck or rail transport of food. We do not discuss these types of comments in this document.

II. What is the legal authority for this rule?

We are issuing this rule under authority of the 2005 SFTA and as directed by section 111(a) of FSMA.

The 2005 SFTA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), in part, by creating a new section, 416 of the FD&C Act (21 U.S.C. 350e). Section 416(b) of the FD&C Act directs us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food in the United States to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416(c) of the FD&C Act specifies that we shall prescribe those practices that we determine are appropriate relating to: (1) Sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping. Section 416(c) of the FD&C Act also states that the regulations are to include a list of nonfood products that may, if shipped in a bulk vehicle, render adulterated food that is subsequently transported in the same vehicle, and a list of nonfood products that may, if shipped in a motor vehicle or rail vehicle (other than a tank vehicle or bulk vehicle), render adulterated food that is simultaneously or subsequently transported in the same vehicle. Section 111(a) of FSMA directed us to issue these sanitary transportation regulations not later than 18 months after the date of enactment of FSMA.

In addition, the 2005 SFTA created new section 402(i) in the FD&C Act (21 U.S.C. 342(i)) which provides that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated. Also, new section 301(hh) in the FD&C Act (21 U.S.C. 331(hh)) prohibits the failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the regulations issued under section 416. The 2005 SFTA also amended section 703 of the FD&C Act (21 U.S.C. 373) by adding section 703(b), which provides that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416.

FDA's authority for this rule is also derived from sections 402(a)(1), (2), and (4) and 701(a) of the FD&C Act (21 U.S.C. 371(a)). Section 402(a)(1) of the FD&C Act provides, in part, that a food is adulterated if it bears or contains any added poisonous or deleterious substance, which may render it injurious to health. Section 402(a)(2) of the FD&C Act provides that a food is adulterated if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity (RAC) or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of 21 U.S.C. 346; if it bears or contains a pesticide chemical residue that is unsafe within the meaning of 21 U.S.C 346a(a); or if it is or if it bears or contains (1) any food additive that is unsafe within the meaning of 21 U.S.C. 348; or (2) a new animal drug (or conversion product thereof) that is unsafe within the meaning of 21 U.S.C. 360b. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. This rule includes requirements that are necessary to prevent food from becoming unsafe, *i.e.*, adulterated under the aforementioned provisions of section 402 of the FD&C Act, due to insanitary transportation practices. These requirements allow for the efficient enforcement of the FD&C Act.

III. What general comments did we receive on the proposed rule?

A. Purpose of This Rule

(Comment 1) We stated in the proposed rule that the goal of this rulemaking is to ensure that transportation practices do not create food safety risks and that this rule builds on current food transport industry best practices. The rule is focused on ensuring that persons engaged in the transportation of food that is at the greatest risk for contamination during transportation follow appropriate sanitary transportation practices. This rule allows the food transportation industry to continue to use best practices concerning the cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment that it has developed to ensure that food is transported under the conditions and controls necessary to prevent contamination and other safety hazards.

Several comments support our intent to provide shippers, loaders, carriers and receivers with the flexibility to continue to utilize appropriate sanitary transportation industry best practices. A comment states that this approach allows companies to tailor their practices, as appropriate and necessary, based on the nature of the food and the transportation conveyance used, and to adopt new practices when there are advances in technology. Other comments agree with many aspects of the proposed rule, but conclude that some aspects need further refinement to reflect current industry best practices.

On the other hand, one comment states that this rulemaking is not necessary and that the food transportation industry, instead, should be given the flexibility to meet the standards placed upon it by the shippers without undue interference, or rules and regulations, that hinder the safe and efficient movement of human and animal food. One comment states that there are no systemic food safety issues related to the sanitary transport of food and that, therefore, this rulemaking is unnecessary.

(Response 1) As stated in the proposed rule, the SFTA requires FDA to issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. We have met this mandate, in part, by incorporating current best practices into this rule to the extent that we believe they are effective in achieving the goal of this rule. We disagree with the comments that stated this rule is unnecessary because Congress found that there was an adequate need to mandate that FDA issue these regulations in the 2005 SFTA and FSMA.

B. What regulatory approach should we take?

(Comment 2) Several comments express concern that the proposed rule applies the same requirements to human food and animal food. Many of these comments state that we should issue a separate rule for the sanitary transportation of animal food that is appropriately risk-based and specific to the types of ingredients and manufacturing processes used for animal food. Other comments state that we should distinguish between sanitary transportation requirements for animal food and human food in this rule to allow it to be reasonable and practical for the animal food industry.

(Response 2) We agree that this rule should more clearly recognize that sanitary transportation practices may differ for different types of food being transported to avoid confusion in its interpretation and application. Accordingly, and as discussed in our responses to Comment 89, we have revised the requirements of this rule for vehicles and transportation equipment (§ 1.906), and for transportation operations (§ 1.908), to make it clear that these requirements take into account the intended use of the vehicle or equipment, *e.g.*, the transportation of animal feed. Also, as discussed in our response to Comment 130, we have also revised the requirements of this rule for transportation operations (§ 1.908) to state that the type of food being transported, *e.g.*, human food or animal feed, must be considered in establishing the applicable sanitary transportation practices.

(Comment 3) One comment states that there are two distinct animal food industries, the pet food industry, which employs standards and practices equivalent or close to those used for human food, and the animal feed industry, for which product is not normally handled with the same equipment used for human food transportation operations. This comment encourages us to recognize the significant difference between the purpose and function of these two "markets" for animal food, so that livestock feed transportation is not held to the same standards as pet food transportation. A related comment encourages us not to establish a pet food standard for all animal food and stated that the final rule should not require significant conversion of equipment used in animal feed sourcing and transport operations to pet food standards which necessitate the use of stainless steel equipment.

(Response 3) We agree that sanitary transportation practices for pet food differ from those for animal feed. The revisions we have made to this rule in § 1.906 and § 1.908, as explained in our response to Comment 2, will allow practices employed for the transport of pet food and animal feed to be appropriately tailored to the unique needs of those operations. This rule, therefore, will not necessitate the conversion of equipment used in animal feed operations to meet standards for pet food.

(Comment 4) Some comments suggest that produce safety could be improved by establishing general requirements under the FSMA produce safety rule for the transportation of produce after it leaves the farm, if the farm assumes the role of either the shipper or the carrier. These comments suggest that these FSMA produce safety requirements should be similar to the practices outlined in the proposed rule for the transport of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control. These comments also state that, by covering produce under a transportation provision in the FSMA produce safety rule, enforcement for sanitary transportation practices would be performed by Agencies already tasked with implementing the produce safety rule. One comment states that regulating the transportation of produce in this manner would provide a single source for compliance requirements and would likely reduce the possibility that any requirements might be overlooked.

(Response 4) The produce safety rule establishes science-based minimum standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious adverse health consequences or death, focusing on the most important routes of on-farm contamination of produce with biological hazards. By contrast this rule requires persons engaged in the transportation of all foods, including fresh fruits and vegetables, to use sanitary transportation practices in their operations to ensure that food is transported under conditions that prevent it from becoming unsafe. The sanitary transportation practices required by this rule are not limited to those that address potential contamination of food with biological hazards, they also apply to other forms of contamination, *e.g.*, with chemical and physical hazards, that could cause food to become unsafe. We believe it is most appropriate to establish requirements related to transportation of produce after it leaves the farm in this rule.

(Comment 5) One comment expresses concern that this rule's requirements would apply uniformly across the entire U.S. food transportation sector, despite the fact that current railroad industry best practices have resulted in very few reported cases of foodborne illnesses directly attributable to rail carriers. Another comment asserts that we should defer issuing this rule as it applies to railroads. It states that, in view of the absence of reported incidents of insanitary food rail transportation and the existing rail industry practices to prevent such incidents, applying the rule to the rail industry is not necessary at this time.

(Response 5) The 2005 SFTA directs us to issue regulations that require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. We are issuing this rule as directed by Congress. It is unlikely carriers who have successfully employed best practices for food transportation, whether they be motor or rail carriers, will need to alter their transportation practices significantly to comply with this rule, although we acknowledge that there are new costs associated with training and recordkeeping.

(Comment 6) One comment identifies smaller box trucks making local deliveries as a particular sanitary food transport problem. The comment states that most of the instances where food transportation problems were found in the 2007 Interstate Food Transportation Assessment Project study (Ref. 6) involved smaller box trucks as discussed in the proposed rule (79 FR 7006 at 7008). The comment suggests that FDA develop an enforcement plan focused on smaller box trucks engaged in local food delivery operations.

(Response 6) As we implement this rule, we will work with our partners, *i.e.*, DOT, and State, local, territorial and tribal officials, to direct our efforts to address the areas of greatest need with respect to practices that create potential food safety risks for local deliveries. To the extent that smaller box trucks making local deliveries fall below the "Non-Covered Business" cutoff of $500,000, we note that these trucks remain subject to the provisions, including the adulteration provisions, of the FD&C Act with regard to their transport of food.

(Comment 7) One comment states that the provisions of this rule are not specific and so broad based that they should be viewed only as non-binding recommendations. It further asserts that the only way we can protect the food supply is by implementing enforceable laws like the Sanitary Food Transportation Act of 1990 and that DOT already has a system in place in which vehicles are inspected wherein they could use an F (signifying food vehicle) on the inspection sticker of the trucks and trailers that transport food.

(Response 7) We reject this interpretation of this rule. The provisions of this rule are not guidance nor are they recommendations. Many of the requirements established in this rule address broadly applicable procedures and practices intended to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements in a way that is most suitable for their practices, as many are already implementing the industry best practices on which the rule is based. Furthermore, Congress enacted the 2005

SFTA to grant FDA, DOT, and USDA shared responsibility over regulating the sanitary transportation of food.

C. How does this rule relate to other FSMA rules?

(Comment 8) Several of the comments express a preference for the farm definition in the proposed transportation rule over the definitions in other FSMA proposed rules because it does not limit the facility's activities to the packing and holding of a farm's own food. These comments recommend that we apply the sanitary transportation rule's farm definition throughout all of the FSMA rules. Conversely, another comment suggests that we use different definitions for entities such as "farms" in the various FSMA rules, allowing us to take a customized approach to each specific rule.

(Response 8) We agree that using a definition of the term "farm" in this rule that, to the extent practicable, is aligned with this term as defined in other FDA regulations, including the regulations we have established under FSMA, would be functionally efficient for us and for stakeholders. We explained in the proposed rule that we tentatively defined the term "farm" differently than it was defined in 21 CFR 1.227(b)(3), which is used to establish which facilities are required to register under section 415 of the FD&C Act (21 U.S.C. 350d), because 21 CFR 1.227(b)(3) applies only to facilities that pack or hold food if the food used in such activities is grown, raised, or consumed on that farm or a farm under the same ownership. We had tentatively concluded that the sanitary transportation practices that would be required by our proposed rule would not be necessary to prevent RACs from becoming adulterated during transportation by farms, regardless of whether the farms are conducting transportation operations for RACs that were grown, raised, or consumed on the same farm or on another farm under different ownership. We therefore tentatively concluded to use a different definition of the term "farm" for purposes of this rulemaking.

In the FSMA preventive controls for human food final rule (80 FR 55908 at 55925), we revised our definition of the term "farm" in 21 CFR 1.227 to clarify the types of activities that are included as part of the definition of the term "facility" and to clarify the scope of the exemption from the registration requirement for "farms" established in section 415 of the FD&C Act. This revised definition no longer requires that farms that pack or hold food only carry out these activities for food that was grown, raised, or consumed on that farm or a farm under the same management. This revised definition now governs the applicability of the provision in this final rule that excludes transportation operations performed by farms from coverage under this rule. We, therefore, have aligned this rule with the revised definition of the term "farm" in 21 CFR 1.227 by revising 21 CFR 1.904 to state that this term has the new meaning contained in 21 CFR 1.227. This action also aligns the definition in this rule with this term as defined in other FSMA rules, *i.e.*, the preventive controls rule for animal food and the produce safety rule.

(Comment 9) One comment urges us to create a party with the same responsibilities as the "importer" in the FSMA Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule who would be responsible for verifying that the practices of foreign suppliers are in compliance with our regulations. The comment states that this person would be responsible for verifying the safe transportation of imported products before and after the products arrive in the United States. The comment explains that in the preamble to the FSVP proposed rule, we stated that the person responsible for verifying the safety of the foreign supplier "has a direct financial interest in the food and is most likely to have knowledge and control over the product's supply chain." The comment asserts that for imported food, the safety of the food transport is inextricably linked with the safety of the supply chain, starting with the foreign supplier. The comment further states that the person with a direct financial interest in the food product is the party most likely to have the knowledge and control necessary to ensure not just the safety of the foreign supplier, but also the safety of the transportation after the food arrives in the United States. The comment argues that there should be consistency between these two rules for imported products.

(Response 9) The 2005 SFTA direct us to issue regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food in the United States to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. It does not direct us to establish requirements for the transport of food destined for the United States before it reaches the United States. Shipments of food destined for consumption in the United States remain subject to the provisions of the FD&C Act, including the adulteration provisions.

(Comment 10) One comment states that the treatment of small businesses in the FSMA rules is not consistent. The comment states that modified requirements, compliance dates, and exemptions have been based on annual sales throughout the FSMA proposed rules, but the annual sales metrics have not been consistent, *i.e.*, the rules have addressed business size alternatively on the basis of total annual sales, rolling averages of total annual sales, numbers of employees, total annual food sales, and total sales in combination with qualified end user sales. The comment recommends that we create a simpler, consistent approach so that businesses can clearly discern whether they must comply with the regulations.

(Response 10) The only provisions of this final rule that are related to the business size or business volume are the number of employees threshold for businesses, other than carriers by motor vehicle, in the definition of a "small business," the annual receipts threshold for carriers by motor vehicle in the definition of a "small business," and the annual revenue threshold in the definition of a "non-covered business."

With respect to the number of employees threshold for businesses that are not carriers by motor vehicle, as explained in the proposed rule (79 FR 7006 at 7014) and the discussion of this definition in section IV.C. of this final rule, this provision is based upon the size based standard (expressed in terms of numbers of employees) that has been established by the U.S. Small Business Administration under 13 CFR 121.201 for most food manufacturers. This provision of the "small business" definition incorporates the same size based standard as we included in the preventive controls final rules for human and animal food.

With respect to the annual receipts threshold for small businesses that are motor carriers, as explained in the proposed rule (79 FR 7006 at 7014) and the discussion of this definition in section IV.C. of this final rule, this provision is based upon the size based standard of the U.S. Small Business Administration for truck transportation firms in 13 CFR 121.201. This provision of the "small business" definition is unique to this rule and has no relation to other FSMA rules, because only this rule establishes requirements for carriers.

With respect to the annual revenue threshold in the definition of a "non-covered business," as we state in our response to Comment 62, we proposed to establish this provision, in part, to treat firms subject to this rule comparably to those firms that are subject to FSMA preventive controls rules. As also explained in the discussion of this definition in section IV.C., we have revised this definition in this final rule to apply the same method for calculating a firm's annual revenue that we used in very small business definitions of the preventive controls rules.

(Comment 11) One comment states that we did not address the issue of routine security measures, such as the use of truck seals, in the proposed transportation rule and other proposed FSMA rules. The comment states that these measures provide a benefit in transportation similar to that of underlying prerequisite programs in the context of a food manufacturer's hazard analysis and critical control point (HACCP) system. The comment further states that these measures need to be addressed by the FSMA rules to ensure that potential contamination risks (that do not rise to the level of the massive, catastrophic threats that are the subject of the proposed FSMA intentional adulteration rule) are addressed.

(Response 11) This suggestion is outside the scope of this rulemaking. We agree that persons engaged in food transportation should consider the use of routine security measures. We have issued guidance on this subject: "FDA Guidance on Food Security Preventive Measures for Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations, and Fluid Milk Processors;" and "FDA Guidance on Food Security Preventive Measures for Food Producers, Processors, and Transporters" (Refs. 17 and 18). However, the purpose of this rule is to establish sanitary transportation practices to be used by shippers, carriers by motor vehicle and rail vehicle, receivers, and other persons engaged in food transportation to ensure that food is not rendered adulterated during transportation, which is distinct from the issue of the security of food transportation. FDA will be addressing food defense concerns in its upcoming final rulemaking on Intentional Adulteration; however, to the extent that certain food defense issues are not covered in the FSMA rulemakings, and it becomes apparent as we implement the rules that there are food defense concerns that would benefit from additional regulation, we will consider initiating such rulemakings in the future.

D. Effect of Other Statutes on the Applicability of This Rule and How This Rule Affects Food Regulated by Other Federal Agencies

(Comment 12) Several comments note that FDA lacks jurisdiction over meat, poultry, and egg products within meat, poultry, and egg product establishments that are subject to USDA regulation and inspection by USDA's Food Safety and Inspection Service (FSIS) under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). Some of these comments ask us to explicitly acknowledge in this rule that USDA has exclusive jurisdiction over meat, poultry, and egg products operations conducted in these establishments and over the meat, poultry, and egg products up until the time these food products leave these establishments. They also observed that the requirements of this rule would only apply to meat, poultry, and egg products after they have left the FSIS-inspected establishments and, therefore, that the requirements of this rule only apply to carriers as they transport meat, poultry, and egg products and receivers of those products, provided that the receiver is not exclusively inspected by FSIS.

In addition to the FDA–USDA jurisdictional issue, some comments state that a new layer of FDA sanitary food transportation regulation is unnecessarily duplicative with respect to the meat and poultry industries because meat and poultry establishments are already subject to FSIS regulations that address the transportation of meat and poultry products (see, 9 CFR part 325 and 9 CFR part 381, subpart S), as well as by guidance issued by USDA. These comments also state that FSIS's existing meat and poultry safety regulations and oversight activities are adequate and sufficiently robust, and are based on established industry best practices. Another comment suggests that we should dispense with any unnecessarily duplicative sanitary food transportation regulation of meat, poultry, and egg products by issuing a waiver, as provided for under this rule, or by establishing a Memorandum of Understanding (MOU) with FSIS that provides for FSIS to regulate transportation of these products from FSIS-regulated facilities.

(Response 12) We agree that FDA lacks jurisdiction for meat, poultry, and egg product activities that occur within meat, poultry, and egg product processing facilities regulated exclusively by USDA. We have consulted with USDA and modified § 1.900(b) in this rule by adding a third category of persons exempt from the requirements of this subpart. In this final rule, § 1.900(b)(3) excludes shippers, loaders, receivers, or carriers when they are engaged in transportation operations of food while the food is located in food facilities as defined in § 1.227, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the FMIA, the PPIA, or the EPIA. However, there are dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both foods regulated by USDA and foods regulated by FDA. In the case of dual jurisdiction establishments, FDA would inspect in accordance with its existing MOU with USDA (Ref. 19).

In addition, we did not tentatively conclude in the proposed rule that USDA guidance on the safe transportation and distribution of meat, poultry, and egg products is not adequate to ensure their safety. Rather, we stated that FSIS does not have requirements that directly address transportation operations for these foods once they leave FSIS-inspected facilities. However, FSIS has regulations that require that FSIS-regulated establishments to address sanitation during transportation, *e.g.*, 9 CFR 416.4(d) and 9 CFR 417.2(a)(1), and this rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices for FSIS-regulated meat, poultry, and egg products.

(Comment 13) One comment opposes applying the sanitary food transportation rule to shell eggs on the grounds that the transportation of shell eggs is already regulated by FDA under 21 CFR part 118, and that the transportation of egg products is already regulated by USDA under requirements established under the EPIA. The comment further states that most shell egg producers also are subject to additional transportation safeguards either because of customers' proprietary specifications or customers' requests that the egg producers participate in voluntary quality-assurance programs, such as the Safe Quality Food (SQF–2000) standards or the United Egg Producer's 5-Star Egg Safety Program.

(Response 13) We disagree with this comment. The transportation requirements in 21 CFR part 118 address only the ambient temperature of vehicles used to transport shell eggs and do not include requirements for the design, condition, and sanitation of the vehicles or specific procedures to ensure that the specified temperatures are consistently achieved. Similarly, USDA's requirements for the transportation and storage of eggs packed for the ultimate consumer (9 CFR 590.50) refer only to the ambient temperature at which shell eggs must be stored and transported. By contrast, this rule addresses the design, condition, and sanitation, as well as the temperature, of vehicles used to transport food.

With regard to customers' specifications and quality assurance programs, many types of foods are subject to customers' transportation specifications and quality assurance programs. However, we cannot rely on them, exclusively and under all circumstances, to keep food safe during transportation because they vary in effectiveness and are not uniformly administered. This rule establishes uniform, nationwide requirements for the sanitary transportation of food, including shell eggs. To the extent that transportation practices are covered under egg quality assurance programs, these egg producers should find it easier to comply with our requirements.

(Comment 14) A few comments ask us to amend this rule to clarify that under section 116(a) of the FSMA, a facility engaged in the manufacturing, processing, packing, or holding of beverage alcohol products is exempt from this rulemaking. The comments also suggest that we should exempt the transport of all bulk or packaged beverage alcohol products from this rule, including the transport of ingredients and the co-products or by-products of beverage alcohol manufacture. The comments state that the language of section 116 of FSMA specifies which sections of the statute apply to a facility engaged in the manufacturing, processing, packing, or holding of one or more beverage alcohol products, and note that unless a rule falls under sections 102, 206, 207, 302, 304, 402, 403 or 404 of FSMA, Congress does not intend for it to apply to a facility engaged in manufacturing, processing, packing, or holding beverage alcohol products. The comments further assert that because section 111(a) of the FSMA, which directs us to issue this rule, is not one of the listed sections, a facility that is exempt under section 116 should also be exempt from the sanitary food transportation rule. Some of the comments also state that we should exempt the transport of alcoholic beverage products, as well as any oversight of their production facilities, from this rule to avoid duplicative regulatory schemes implemented by both FDA and the U.S. Tax and Trade Bureau (TTB).

(Response 14) There is nothing in FSMA that indicates that transportation operations for beverage alcohol should be exempt from the requirements of this rule. Section 111(a) of the FSMA only creates a deadline for the implementation of the 2005 SFTA final rule, and nothing in the FSMA otherwise addresses the 2005 SFTA. Therefore, it seems that, based on a plain reading of the statute, transportation operations for beverage alcohol can be covered by this rule. In addition, we are not aware of TTB regulatory requirements that would duplicate the requirements of this rule. However, this final rule, as provided under the revised definition of "transportation operations" in § 1.904, does not apply to the transportation of food fully enclosed by a container that does not require temperature control to prevent it from becoming unsafe. This provision essentially excludes packaged beverage alcohol products from coverage under this rule.

(Comment 15) One comment asks that we consider issues regarding the rejection of produce shipments under this rule that are also subject to the Perishable Agricultural Commodities Act (PACA). The comment states that under the PACA, sellers and buyers must legally ship and accept the quantity and quality of produce specified in their contracts, and receivers must accept produce that is damaged and decayed, up to a certain percentage, depending on the product's grade standards. The comment contemplates a situation where a receiver would be required to accept shipments under the PACA, but, according to the comment, might be required to reject them under this rule for deviation from quality standards set by the shipper.

(Response 15) This rule does not require a receiver to reject a shipment that is transported under conditions that deviate from those specified by the shipper to the carrier and loader in accordance with § 1.908(b)(1). As explained in our response to Comment 129, the rule establishes requirements for shippers, loaders, carriers, and receivers in § 1.908(a)(6) that precludes the sale or distribution of any food subject to this rule where there is an indication of a material failure of temperature control or other conditions during transportation that may render the food unsafe, unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. Contrary to the comment's assertions, this rule does not address the disposition of any produce delivered to a receiver that might deviate from quality standards set by a shipper.

E. Other Comments

1. Contractual Reassignment

(Comment 16) Several comments asserted that, to reflect common industry practice, we should explicitly recognize that companies that bear legal responsibility for compliance with this rule may contractually assign specific tasks, *e.g.,* vehicle inspections or taking a temperature measurement, to an alternative or better suited entity. Several comments state that we acknowledged the potential for parties to contractually allocate tasks in the preamble discussion of the proposed rule (79 FR 7006 at 7014) and that we should explicitly recognize in the final rule that shippers, carriers, and receivers may enter into contracts that allocate tasks either between them or to another entity. For example, one comment states that a carrier should be able to rely exclusively on a receiver to take the temperature of a refrigerated food load upon delivery to assess the potential for temperature abuse during transport given that the receiver may already be engaging in this activity for its own purposes. Several comments state that firms that contractually reassign tasks should maintain records that FDA could review during inspections to document these contractual agreements. One comment states that there may be entities involved in food transportation other than those that would be subject to the proposed rule, such as warehouses, that might contractually assume some of the requirements described in the proposed rule.

(Response 16) We acknowledge that industry practice is to alter, by contract, the tasks assigned to shippers, loaders, carriers, and receivers in this rule. Therefore, we also explicitly recognize that companies that bear legal responsibility for compliance with this rule may contractually assign specific tasks, *e.g.,* cleaning a vehicle or communicating previous loads hauled, to an alternative entity. We also understand that industry best practice is to memorialize the assignment of duties in a transportation operation with a written contract.

The duty to comply with the provisions in this rule can be reassigned via contract among parties covered by this rule (*e.g.,* as described in § 1.908(b)(5) where the shipper assigns responsibilities such as monitoring temperature during transit via written contract to a carrier). We have further clarified this point by adding language at § 1.908(a)(1) that states that an entity subject to this rule (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this rule to another party subject to this rule. This provision also states that the written agreement is subject to the records requirements of § 1.912. Further, parties may accomplish their duty to comply with provisions in this rule by assigning tasks to parties not covered by this rule, as long as such assignment is covered by a written contract (*e.g.*, a carrier may contract with a truck wash station to wash a bulk tanker, where the truck wash station is not an entity that is covered by this rule). If responsibility under this rule is assigned via contract to another party covered by this rule (first example, aforementioned), FDA would consider the terms of the contract in determining who is responsible for compliance. If a task under this rule is assigned via contract to a party who is not covered by the rule (second example, aforementioned), FDA would hold the party covered by the rule ultimately responsible for compliance with the provisions of the rule. Any written agreements assigning duties in compliance with this rule will be subject to the recordkeeping provisions in § 1.912.

2. Intrastate Transportation

(Comment 17) One comment states that the application of this rule to both intrastate and interstate shipments would create consistent expectations among parties engaged in food transportation. Furthermore, the comment suggests that we consider addressing in this rule a common practice among the parties engaged in food transportation whereby they engage in a separate contract for the transportation of food, as authorized by 49 U.S.C. 14101(b). The comment states that because there is currently no standard transportation contract, parties are free to agree to any and all terms that they choose, and the various State laws apply to those terms. Further, the comment asked whether parties can shift responsibilities, agree to terms more or less onerous, and change the meaning of this rule by contract. The comment states that we should clarify whether the rule cannot be modified by contract or specify what parts can be modified. The comment also states that leaving these questions unsettled in the final rule might result in numerous State contract claims related to this rule.

(Response 17) We agree that the application of this rule to both intrastate and interstate shipments would create consistent expectations among parties engaged in food transportation.

Further, we acknowledge that under the provisions of 49 U.S.C. 14101(b), carriers by motor vehicle may "expressly waive any and all rights and remedies under [that] part for transportation covered [by a contract between that carrier and a shipper]." However, the purpose of this rule is not to address the ability of parties to contract under that provision. The purpose of this rule is to ensure that shippers, loaders, carriers, and receivers use practices that ensure the sanitary transportation of human and animal food. Therefore, as discussed in the previous comment, the roles being played by the particular parties involved in the transportation of food can be shifted among the parties within the contractual relationship However, entities covered by this rule cannot, via contract or otherwise, either change the meaning of the rule or establish sanitary transportation requirements that are less onerous than those contained in this rule.

(Comment 18) One comment states that intrastate activities should be exempt from the requirements of this rule. It asserts that the paperwork burden required by this rule would be onerous for local bulk animal feed facilities and that complying with this rule would make it difficult for these types of facilities to remain in business. The comment further states that the intrastate transportation of commercial animal feed historically has presented little to no risk to humans and animals.

(Response 18) We disagree that intrastate transportation activities should be exempt from this rule. As we noted in the proposed rule, section 416(b) of the FD&C Act directs us to create regulations to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated. The scope of section 416(b) is not limited to interstate commerce. We are sensitive to the concerns voiced by this comment about the burden this rule might impose upon small facilities. As we discuss in sections IV.E.2 and 5, we have revised the requirements regarding the exchange of information between shippers and carriers (§ 1.908(b) and (e)), which in many cases will reduce or eliminate paperwork burdens imposed on parties subject to this rule, including facilities engaged exclusively in the intrastate shipment of bulk animal feed. In addition, feed facilities engaged in intrastate transportation operations are not subject to this rule if they are a "non-covered business" as defined in this rule. This final rule establishes appropriate requirements for such facilities and will not impose undue cost or paperwork burdens. Since the rule has its basis in industry best practices, many persons should be in substantial compliance with its provisions and should not find compliance burdensome. Accordingly, this comment does not persuade us that it would be appropriate or in keeping with the purpose of this statute to exclude intrastate activities from the scope of this rule.

3. Enforcement Issues Related to This Rule

(Comment 19) We received many comments regarding the enforcement of this rule. The comments cover a broad range of topics, such as: The need for clarification of the roles of various Agencies including DOT and State and local regulatory authorities in enforcing the rule; FDA's need to establish enforcement partnerships with other Agencies; how variations in the applicability of this rule (*e.g.*, those entities that are subject to the rule and those that are not, and the effects of the varying size of the entities covered by the rule) will be addressed; whether enforcement during transportation, as opposed to at points of origin and destination, is practical and/or necessary to ensure food safety; how enforcement actions might vary depending on the severity of a violation and the potential threat posed to food safety resulting from a violation; the training that inspectors will likely need to properly enforce this rule; how inspections will be carried out without compromising the safety of the food shipment; and the need for enforcement guidance for industry. Some comments express concern about unequal enforcement of this rule directed toward trucking as compared to railroad operations, because regulators can more readily develop and execute truck surveillance and inspection programs. Comparable surveillance and inspection activities are more difficult for railroad operations, *e.g.*, access to rail yards may be more limited and trains cannot be stopped for inspection during transit. One comment addresses the importance of ensuring that enforcement has a minimal impact on international trade, especially in the case of rail carriers operating between the United States, Canada, and Mexico. Some comments express concern that we currently lack the resources to carry out inspections and that we will face staffing and training challenges in operationalizing this rule to achieve consistent enforcement of the rule.

(Response 19) The Secretary of Transportation, in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture, is required by section 5701(a)(1) of the 2005 SFTA to establish procedures for transportation safety inspections to identify suspected incidents of contamination or adulteration of: Food in violation of regulations issued under section 416 of the FD&C Act; carcasses, parts of carcasses, meat, meat food products, or animals subject to detention under section 402 of the FMIA (21 U.S.C. 672) and the DOT's food transportation safety inspection requirements that appear at 49 U.S.C. 5701; and poultry products and poultry subject to detention under section 19 of the PPIA (21 U.S.C. 467a). The 2005 SFTA further states in section 5701(b) that the Secretary of Transportation shall promptly notify the Secretary of Health and Human Services or the Secretary of Agriculture, as applicable, of any instances of potential food contamination or adulteration of a food identified during DOT transportation safety inspections. We note that DOT and USDA have jointly produced a training video, entitled "Considerations for the Safe Transportation of Food Video," that is available via the Department of Homeland Security at the University of Tennessee Knoxville's Web site: *http://www.vet.utk.edu/cafsp/online/ftsvideo.php.* DOT also has trained its enforcement officers to report any food safety violation they encounter to FDA or USDA, depending on the nature of the food being transported. We will work with DOT to support these inspection efforts. However, we note that while DOT has authority to conduct transportation safety inspections for the purpose of identifying suspected incidents of food shipments that are not in compliance with this rule and is authorized by section 416(f) of the FD&C Act to provide assistance upon request by FDA in the enforcement of this rule, FDA will generally be responsible for taking action when food or persons are found to be in violation of the statutes and regulations it administers.

We intend to allocate our resources for the enforcement of this rule by following up on information that DOT provides us or by initiating inspections and investigations. These comments raise issues that we will consider when developing enforcement strategies. The details of our prospective enforcement strategies, however, are beyond the scope of this rulemaking; however we believe that the impact of our enforcement activities upon international trade will be minimal since this rule allows the transportation industry to continue to use existing practices that have proven to be effective for the safe transportation of food. We know that we will need to address staffing and training needs, and we will seek to establish partnerships with other Federal Agencies and with State, local, and tribal governments to implement this rule. We also will communicate with the public, including with regulated industry, as appropriate, throughout the process of developing and implementing our enforcement efforts for this rule.

4. Intra-Corporate Operations

We received several comments asking us to include provisions in this final rule for food transportation operations that are conducted under the ownership or operational control of a single corporate/legal entity, *i.e.,* food shipments involving shippers, loaders, carriers, and/or receivers that are corporate subsidiaries or affiliates of a common corporate parent company/legal entity. The comments refer to these types of activities alternatively as "intra-corporate" or "intra-company" food transportation operations.

(Comment 20) Several comments state that intra-corporate transportation operations should be completely and expressly exempt from this final rule. Some of these comments suggest that we should define the term intra-corporate/intra-company in § 1.904 of the final rule and exempt these types of activities from the definition of "transportation operations" as that term is defined in § 1.904. Some of the comments ask us to exempt intra-corporate transportation operations by issuing a waiver as provided for under §§ 1.914 and 1.916 of this final rule. Most of these comments assert that intra-corporate shipments typically are conducted in accordance with integrated, intra-corporate Standard Operating Procedures (SOPs) and good sanitary food transportation practices and therefore should be exempt from the final rule. Some of the comments argue that food transportation operations that are predominantly, but not entirely intra-corporate, for example, in which a shipper and a receiver share a common corporate ownership, but in which the loader or carrier might be an independent, third-party entity operating under a contract with the shipper, also should be entirely and expressly exempt from this final rule.

Some of these comments assert that we should exempt intra-corporate food shipments from this rule because we contemplated exempting similarly situated entities under our FSMA FSVP proposed rule (78 FR 45730 at 45743). Two comments argue that exempting all intra-corporate food transportation operations from this rule is warranted because intra-corporate transfers would be addressed under the FSMA preventive controls rules for human and animal food. These comments assert that subjecting intra-corporate shipments to additional regulation and recordkeeping requirements under this sanitary food transportation rule therefore would be unnecessary and redundant.

One of the comments observes that the SFTA of 2005 and § 1.904 of the proposed rule define the term "transportation" to mean "any movement in commerce by motor vehicle or rail vehicle." The comment asserts that intra-corporate food shipments therefore should be exempt from this rule because, for example, food shipped between facilities owned, leased, or operated by the same corporate entity "does not enter the stream of commerce."

(Response 20) We decline to establish a blanket exemption from all of this rule's requirements for food transportation operations that are conducted between shippers, loaders, carriers, and/or receivers that are part of the same corporate/legal entity either by revising the definition of "transportation operations" in the final rule, by issuing a waiver for intra-corporate shipments, or by any other mechanism. We conclude that the fact that shippers, loaders, carriers, and/or receivers may be operating within a unified corporate/legal entity or sanitary food transportation system does not necessarily ensure that all of the involved parties are operating in compliance with the portions of section 402 of the FD&C Act that are relevant to this rulemaking. While we acknowledge that parties involved in intra-corporate food transportation operations can lessen their recordkeeping burden by adopting a unified, company-wide approach to sanitary food transportation operations, *e.g.,* by creating comprehensive SOPs that are to be followed by shippers, loaders, carriers, and/or receivers that operate under common corporate ownership or control, such unified, company-wide SOPs must ensure that the food is transported in compliance with the requirements of this final rule. We address the use of contracts to assign specific food transportation tasks to independent, third parties in our response to Comment 16.

In the FSVP final rule, we declined to establish "an exemption from the FSVP requirements for food that an importer obtains from a foreign supplier that is part of the same corporate structure as the importer," and we further declined "to establish an exemption from the FSVP requirements where the foreign supplier and importer may otherwise be affiliated, and where the foreign supplier and importer are part of the same company-wide 'approach' to food safety" (80 FR 74225 at 74255–56).

We also decline to exempt intra-corporate food transportation operations from this rule on the grounds that such activities will be covered by the requirements of the preventive controls rules for human and animal food. The primary purpose of the preventive controls rules is to establish modern science- and risk-based preventive controls requirements for the manufacturing, processing, packing, or holding of human and animal food. Although facilities under the preventive controls rules may identify refrigeration during transport as a preventive control, for example, the preventive controls rule, unlike this final rule, does not directly regulate carriers. We also note that SFTA was signed into law in 2005 and FSMA was signed into law in 2011. If Congress had intended for FSMA's preventive controls rules to supplant the sanitary food transportation statutory requirements set forth in SFTA under any circumstances, including but not limited to intra-corporate food shipments, Congress presumably would have stated so explicitly in FSMA's statutory language.

Finally, we also decline to completely exempt intra-corporate food transportation operations from this final rule on the commenter's theory that food shipments between shippers, loaders, carriers, and/or receivers that share a common corporate ownership do not fall within the rule's definition of "transportation" because such food shipments do not enter the stream of commerce. Although not explicitly stated in the comment that asserts this theory, the comment appears to suggest that the shipment of food between entities that operate under a common corporate ownership or control does not enter into the stream of "commerce" presumably because the food is not being offered for sale between the parties involved in the transportation operations. We conclude that this interpretation of the 2005 SFTA's statutory definition and the parallel definition of "transportation" in § 1.904 of this final rule is incorrect. The 2005 SFTA does not define the term "in commerce" and therefore does not explicitly limit the scope of the rule, for example, only to those transportation operations that involve the shipment of food that is offered for sale.

(Comment 21) We received several comments asking us to apply modified requirements regarding this rule's information sharing and recordkeeping provisions to shippers, loaders, carriers, and/or receivers engaged in intra-corporate food transportation operations. These comments state, for example, that to require a shipper under this rule that owns its own carrier fleet to provide to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicles and transportation equipment would be redundant and serve no purpose because the information sharing required by this rule, under these circumstances, would presumably already be established by written intra-corporate food transportation SOPs.

Some of these comments assert that a precedent for exempting intra-corporate food shipments from the information sharing and recordkeeping provisions of this rule can be found in the recordkeeping final rule that we issued under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), at 21 CFR part 1, subpart J.

(Response 21) We agree with these comments and have revised the regulatory text accordingly. Section 1.908(a)(5) of this final rule stipulates that as an alternative to meeting this rule's applicable requirements, shippers, receivers, loaders, and carriers that are under the ownership or operational control of a single legal entity may conduct transportation operations in conformance with common, integrated, written procedures that ensure the sanitary transportation of food consistent with the rule. Section 1.908(a)(5) also states that these written procedures are subject to the records requirements of this rule in § 1.912, which are discussed in section IV.G of this document.

Finally, as we already mentioned earlier in this document, some of the comments invoked the Bioterrorism Act recordkeeping rule as a precedent for granting the revised information sharing and recordkeeping requirements of this rule for intra-corporate food transportation operations. As we explained in the preamble to the Bioterrorism Act recordkeeping rule, "intra-corporate" interactions, for purposes of the implementation of that rule, are limited to interactions between entities that are part of a "vertically integrated company," for example, a food manufacturer that owns its own suppliers, carriers, distributors, and food retail outlets and, therefore, never releases the food to persons outside of its vertically controlled production path (69 FR 71562 at 71568–71569, December 9, 2004).

The definition of a vertically integrated company as used in the Bioterrorism Act recordkeeping rule is narrower in scope than the definition of "intra-corporate" in this rule. As we explain in our February 2012 guidance to industry entitled "Questions and Answers Regarding Establishment and Maintenance of Records by Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)" (Ref. 20), two corporate entities that have the same controlling corporate parent are not always part of a vertically integrated company. They may be legally distinct persons, for example, and therefore would not be exempt from the Bioterrorism Act rule's recordkeeping requirements. Similarly, two corporate subsidiaries that are legally distinct persons, but that are managed operationally as a single entity, would not be exempt from the Bioterrorism Act recordkeeping rule. We conclude that the information exchange and recordkeeping provisions set forth in § 1.908(a)(5) of this final rule are appropriate because shippers, carriers, receivers, and loaders operating under the control of a single legal entity can effectively use common integrated written procedures that prescribe sanitary food transportation practices. Accordingly, the provisions set forth in § 1.908(a)(5) of this rule will not be strictly limited to vertically integrated companies, like the Bioterrorism Act's recordkeeping rule.

(Comment 22) One comment asks us to exempt from this final rule's information exchange and recordkeeping requirements food transportation operations that involve shipments of food from centralized charitable food distribution centers that act as shippers, and sometimes also carriers, to member food banks that are separate legal entities, but are closely affiliated with the shippers. The comment also asks us to exempt shipments between food banks. This comment asserts that these types of operations are similar to intra-corporate food transportation operations and, therefore, adherence to this rule's information exchange and recordkeeping requirements should not be required because internal written SOPs are sufficient for ensuring the sanitary transportation of food between these types of entities.

(Response 22) We decline to exempt food transportation operations that involve shipments from centralized charitable food distribution centers to food banks, as well, as food shipments between food banks, from this rule's information exchange and recordkeeping requirements. The commenter describes itself as being a national, domestic hunger relief charity that acts as a shipper to distribute food to and through a network of 200 member community food banks. The comment also states that the individual food banks that form the network "are separate legal entities," but are "closely affiliated with the national organization." We decline to exempt these types of transportation operations from this rule because we do not believe that they are comparable to intra-corporate food transportation operations in which shippers, loaders, carriers, and/or receivers operate under the ownership or operational control of a single corporate/legal entity. The commenter and its network of independent food banks are "affiliated" only in the sense that they cooperate closely to advance their shared mission of delivering food assistance to people in need.

However, we have made revisions in this final rule that may lessen the information sharing and corresponding records requirements for organizations such as the ones described by this comment. As we note in our response to Comment 124, we have revised the information sharing provisions in § 1.908(b)(1) to only require one-time notification to the carrier and when necessary, to the loader, by the shipper, unless the design requirements and cleaning procedures required for sanitary transport change because of the type of food being transported. In addition, as we note in our response to Comment 129 and Comment 134, we have revised § 1.908(b)(2) to recognize that the specification of pre-cooling and operating temperature parameters by the shipper to the carrier, and to the loader, may not be necessary for transportation operations conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances.

5. Lists of Nonfood Cargo That May Adulterate Food

We requested comments in the preamble to the proposed rule in response to our tentative decision not to identify and include, in this rulemaking, specific nonfood products that, under all circumstances, may adulterate food subsequently hauled in bulk or non-bulk vehicles. We also requested comment on our tentative conclusion that issuing guidance instead, regarding how some transportation practices may affect the potential for nonfood products to adulterate food products, and would be helpful to the transportation industry.

(Comment 23) Many comments support our decision not to issue lists of nonfood items that may adulterate food if transported simultaneously with food in a non-bulk vehicle, or prior to the transport of food in a bulk vehicle. Several comments agree with our tentative conclusion that issuing guidance regarding how specific transportation practices may affect the potential for nonfood products to adulterate food products would be helpful to the transportation industry. One comment states that the oilseed industry already uses lists of acceptable and unacceptable previous cargos to prevent the adulteration of edible oils during transport and encourages us to incorporate these lists as reference documents in this rulemaking or to establish corresponding guidance documents.

(Response 23) Based upon these comments, we affirm our decision not to include lists of nonfood items that may adulterate food if transported simultaneously with food in a non-bulk vehicle, or prior to the transport of food in a bulk vehicle, as part of this rulemaking. However, we will consider the utility of using such lists as references in any guidance we may issue on this subject in the future.

6. Need for Guidance

(Comment 24) Several comments express the need for guidance documents related to this rule. These comments state that guidance will be important for explaining our expectations (*e.g.,* what measures are "effective" or "adequate"). Some comments state that, we should provide specific guidance for foreign individuals and entities to clarify who would be responsible for complying with the rule in complex transportation operations involving international shipments into the United States. In addition, a comment states that specific quantitative requirements should be included in guidance rather than in this rule to avoid implementation difficulties.

(Response 24) We agree that guidance are important for helping stakeholders to understand the application of this rule to their operations. As we note elsewhere in this document, we may issue future guidance, as resources allow, regarding issues such as the granting of waivers, transportation activities performed by farms, and how transportation practices may affect the potential for the adulteration of food products by nonfood products during transportation operations. We will consider whether guidance on these or other matters would be useful to clarify measures that entities engaged in the transportation of food may take to comply with this rule. We would not include requirements in any guidance because under our good guidance practices regulation (21 CFR 10.115), guidance documents do not establish legally enforceable rights or responsibilities.

(Comment 25) A comment addressing the transportation of RACs by farms agrees with our tentative conclusion in the proposed rule that the sanitary transportation practices that would be required by this rule are not necessary to prevent RACs from becoming adulterated during transportation by farms. However, to minimize the potential for adulteration, this commenter recommends that we develop a guidance document on good transportation practices, as well as user-friendly education materials. The comment suggests that such guidance should stress the importance of cleanout procedures in non-dedicated farm transportation conveyances and equipment used to haul RACs and other products, and provide sample clean-out procedures for such conveyances. The comment also suggests that the guidance could encourage farms that transport RACs to inform receivers about the previous load hauled in the conveyance.

(Response 25) We discussed the exemption of transportation activities for RACs performed by farms from this rule in the proposed rule (79 FR 7006 at 7016) and noted that the diversity of farms and their transportation operations pose challenges in developing mandatory requirements via rulemaking that would be broadly suitable and meaningful for this sector of the food transportation industry. As we discuss in Comment 79, we have revised this final rule to provide that all transportation activities performed by a farm are not subject to this rule. However, we agree that issuing a guidance document on farm transportation operations may be useful in setting forth good transportation practices, given the diverse practices that occur within this sector. We, therefore, intend to consider establishing such guidance and will consider the role that we might be able to play in promoting educational and training activities to address this issue.

7. Preemption

(Comment 26) Some comments expressed concern with the preemption provision of the 2005 SFTA and its potential impact on any State with existing transportation requirements. One comment stated that this rule should be flexible enough to permit State laws to stay in effect if the State law is stronger and its enforcement is superior to what is being achieved under this rule. Some of these comments asserted that the statutory exclusions in the coverage of the 2005 SFTA, *e.g.*, its non-coverage of barge transport, in combination with the preemption provision could weaken existing State activities and regulation of industry and prevent States from developing a unified sanitary transportation regulation.

(Response 26) As we stated in the proposed rule (79 FR 7006 at 7032), the 2005 SFTA includes an express preemption provision at section 416(e) of the FD&C Act, which provides that a requirement of a State or political subdivision of a State that concerns the transportation of food is preempted if: (1) Complying with the requirement of the State or political subdivision and with a requirement of section 416, or with a regulation issued under section 416, is not possible; or (2) the requirement of the State or political subdivision as applied or enforced is an obstacle to accomplishing and carrying out section 416 or a regulation issued under section 416. Section 416(e) of the FD&C Act further provides that the express preemption provision applies to transportation that occurs on or after the effective date of regulations issued under section 416. This express preemption provision applies to the requirements of this final rule upon their becoming effective. Nonetheless, a State law, including unified State laws, should States wish to adopt such laws, concerning the sanitary transportation of food by motor vehicle or rail vehicle, is not preempted if such laws do not fall under either section 416(e)(1) or (2) of the FD&C Act. Furthermore, it is highly unlikely that any State law addressing transportation operations not subject to the 2005 SFTA, *e.g.*, barge transport, would fall within the scope of the 2005 SFTA's preemption provision. In most cases, a more stringent provision in State law would not be preempted.

(Comment 27) Some comments urge us to affirm that this rule does not preempt related State laws when they are "in addition to" Federal regulation and do not present an obstacle to advancing the purposes of SFTA. The comments further state that we should construe the preemption clause in the SFTA of 2005 narrowly and that we should work in tandem with State authorities by treating this regulation as a floor, and not a ceiling, for State public health measures such that States wishing to enact sanitary food transportation requirements that are more rigorous than those imposed by this rule will be permitted to do so. These comments state that there are two ways that a Federal authority can block State regulation—either by "conflict (or obstacle) preemption" or by "field preemption"—and the comment stated that the language in the SFTA is an example of the former. Conflict preemption only applies when a person or entity cannot satisfy both Federal and State law, and where State law is an obstacle to Federal goals.

(Response 27) Under section 416(e) of the FD&C Act, this rule does not preempt State laws or laws of a political subdivision regarding sanitary transportation of human and animal food unless complying with those laws and this law is impossible, or the requirement of the State or political subdivision as applied or enforced is an obstacle to carrying out this law. Section 416(e) of the FD&C Act further provides that the express preemption provision applies to transportation that occurs on or after the effective date of regulations issued under section 416.

We agree with the commenters that conflict preemption could apply to any State laws governing sanitary food transportation that would make it impossible to simultaneously comply with this rule. In addition, another aspect of conflict preemption could apply under a "frustration of purpose" or "obstacle" theory, whereby a State law requiring sanitary transportation practices would be preempted to the extent the State law frustrates the purpose of, or presents an obstacle to accomplishing the purpose of, this rule. Whether a State requirement is preempted by Federal law depends on specific factual situations. Therefore, although some State requirements may be preempted by Federal law, this law does not prevent States from developing sanitary transportation regulations at the State or local level.

8. Issuance of Sanitary Transportation Supplemental Proposed Rule

(Comment 28) Some comments ask us to publish a revised proposed rule or an interim rule before proceeding to a final rule because of anticipated, significant changes resulting from comments that we received in response to the proposed rule, as well as potentially significant changes in the other, interrelated FSMA rules. One comment states that because the FSMA rules are dependent on one another, all proposed FSMA rules should be issued concurrently so that a concurrent evaluation and comment period may be conducted. Some comments state that re-proposal and a second opportunity for public comment also is warranted because implementation of the sanitary transportation rule will require the complex coordination of efforts among multiple Federal Agencies.

(Response 28) We considered these comments requesting that we issue a supplemental proposal. This final rule includes numerous revisions to the proposed rule. These revisions, however, better achieve our stated objective in the proposed rule to align the provisions of this rule with current safe food transportation practices and to allow industry to continue to use existing practices that have proven to be effective. The revisions we made to this rule are also a logical outgrowth from the proposed rule and are supported by comments that we received in response to the proposed rule. Therefore, we have determined that issuing a supplemental proposal of the rule is not necessary.

We also do not believe that we need to issue a supplemental proposal because implementation will require complex coordination among multiple Federal Agencies. We have sufficiently addressed in our responses to Comment 12 and Comment 13 the application of this rule to food that is subject to the regulatory authority of USDA. In addition, while section 5701 of the 2005 SFTA directs DOT to establish procedures for transportation safety inspections for the purpose of identifying suspected incidents of contamination or adulteration of food during transport in violation of this rule, we do not consider any coordination that we must do with DOT on enforcement to be particularly complex, such that it would have benefited from an additional opportunity for public comment. Therefore, we have determined that issuing a supplemental proposal to consider further aspects of this rule that are relevant to our interactions and relationships with other Federal Agencies is not necessary.

With regard to the suggestion that we should re-issue all seven of the FSMA foundational proposed rules simultaneously for comment, we agree that this might have been helpful to commenters. However, given our deadlines under a consent decree for the seven rules (Ref. 21), this was not possible. We also believe that stakeholders were given adequate opportunity to comment on the proposed rules, particularly those that are interrelated and were issued simultaneously as supplemental proposed rules in September 2014.

9. Retrospective Review

(Comment 29) One comment states that in line with the requirements of Executive Order 13563, the Office of Management and Budget's (OMB's) implementation memo for that Executive order (Ref. 22), and OMB's 2013 Report to Congress (Ref. 23), it is clear that FDA should incorporate specific plans for retrospective review and ex post evaluation into the text of its final rule. The comment also suggests that given the uncertainty of the underlying data used to formulate the provisions of this rule, we commit to measuring the actual effects of the regulation and use the data we collect during the implementation of the rule to annually review whether the standards are having their desired effects.

(Response 29) We disagree. As discussed in the Final Regulatory Impact Analysis for this rule (Ref. 24), we have examined the impacts of the proposed rule under Executive Orders 13563 and 12866, in relevant part. Section 6 of Executive Order 13563 addresses retrospective analysis of existing rules by agencies, but the Executive order does not require that agencies include retrospective review plans in the codified text. FDA is committed to reviewing its rules to ensure their implementation is effective.

10. Transportation by Modes Other Than Motor Vehicle and Rail Vehicle

(Comment 30) One comment expresses concern about gaps in FDA's authority to regulate different types of food transport conveyances under the 2005 SFTA. The comment notes that the statute specifically limits our regulatory authority to the transportation of food by motor carriers and rail vehicles, excluding transportation by barge or ship and by air. The comment asserts that these omissions create critical weaknesses in the sanitary food transportation system because significant amounts of animal feed grain are transported by barge or ship within the United States and because highly perishable food products are frequently transported by aircraft. Another comment recommends that we explicitly state in this rulemaking that these additional conveyances are excluded and provide a rationale for their exclusion.

(Response 30) The 2005 SFTA, as passed by Congress and signed into law by the President of the United States, expressly mandates that FDA issue regulations to "require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices . . . to ensure that food is not transported under conditions that may render the food adulterated" (21 U.S.C. 350e(b)). We do not believe that we need to issue any confirmatory statements or rationales in response to these comments because the relevant 2005 SFTA statutory language is plain and clear on its face. The 2005 SFTA does not mandate that we issue regulations applicable to the sanitary transportation of food by any other conveyances, including barges or ships and aircraft. However, if we find that there is a public health need for us to regulate air and barge or ship transportation, we will consider whether we want to pursue covering these routes under a non-SFTA authority in the future.

11. Waivers

We stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to the following classes of persons:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products; and
- Food establishments, *i.e.,* retail and food service operations, holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment.

We stated our intent to separately publish in the **Federal Register,** at the time of publication of this final rule, waivers and the reasons for the waivers for these two classes of persons from the applicable requirements of this rule. We requested comment regarding whether these proposed waivers could result in the transportation of food under conditions that would be unsafe for human or animal health, or could be contrary to the public interest. We did not receive any such comments.

However, we did receive comments requesting that we modify or expand the scope of these waivers beyond that which we discussed in the proposed rule. While we intend to publish waivers in the **Federal Register** addressing the aforementioned classes of persons prior to the compliance date of this final rule, we are evaluating these comments to determine whether we should modify either of these two waivers as requested, and we intend to post a notice on our Web site of our reasoning regarding the scope of these prospective waivers at the soonest possible date. We will also discuss, in this subsequent notice, our thinking on comments we received asking us to consider publishing an additional waiver for transportation operations for molluscan shellfish for entities that hold valid State permits under the National Shellfish Sanitation Program.

(Comment 31) We received comments that we should acknowledge Tribal food codes in addition to state and local food codes in our discussion of waivers and that we should refer to Tribal governments in this final rule in every instance in which we mention State or foreign governments.

(Response 31) We acknowledge that tribal authorities, as well as state and local government agencies, can issue permits to food establishments under their relevant regulatory authority. In light of comments, throughout this final rule we explicitly recognize Tribal governments as partners we intend to work with in the implementation of this rule,*e.g.,* as regulatory authorities we may partner with in future efforts to train regulators (see Comment 6, Comment 19, Comment 159, and Comment 176).

IV. What comments did we receive on the specific provisions of the proposed rule?

A. Who is subject to this subpart? (§ 1.900)

In table 5 we outline the revisions we have made to § 1.900 in finalizing this rulemaking. Following the table we respond to comments about these provisions.

TABLE 5—§ 1.900 WHO IS SUBJECT TO THIS SUBPART?

Proposed section (§)	Description	Revision
1.900(a)	Specifies that, except for certain exclusions and exceptions, this rule applies to shipper, loaders, carriers, and receivers engaged in transportation operations.	Added "loaders" to the list of covered entities.
1.900(b)(1)	Specifies that the provisions do not apply to food that is transshipped through the United States to another country.	No revisions.
1.900(b)(2)	Specifies that the provisions do not apply to food that is imported for export in accordance with 801(d)(3) and that is neither consumed or distributed in the United States.	Added "in accordance with section 801(d)(3) of the FD&C Act" to the regulatory text for clarity.
1.900(b)(3)	Specifies that the provisions do not apply to food in facilities regulated exclusively, throughout the entire facility, by USDA.	New provision.

(Comment 32) One comment expresses concern about whether the responsibilities that apply to persons subject to this rule would apply to a specific, individual person rather than to an entity. The comment notes that we indicated in the proposed rule that the intent of the rule is to establish accountability at the individual level for ensuring that transportation operations comply with the rule's requirements. However, the commenter asserts that it is not appropriate to place all responsibility onto a single individual. The comment supports having a qualified individual supervise and provide general oversight, but requests confirmation that the term "person" used in this rule refers to legal persons—including corporations.

(Response 32) The statement that this comment references from the proposed rule (79 FR 7006 at 7018) addresses the proposed requirement in § 1.908(a)(2) that responsibility for ensuring that transportation operations are carried out in compliance with all requirements of this rule must be assigned to competent supervisory personnel. That specific requirement does designate an individual as being responsible for this requirement, but we did not state that the intent of the rule is to establish accountability at the individual level for compliance with all requirements of the rule. The term "person" as used in this rule will include "individuals, partnerships, corporations, and associations."

(Comment 33) One comment asked us to affirm that, for cheese exported to the United States under "freight on board" (FOB) contracts, the shipper is not responsible under this rule once the goods are delivered to a warehouse in the United States. FOB contracts specify that, once the goods have been turned over to the transporting company, the purchaser assumes the risk of loss as defined by the Agreement on International Commercial Terms.

(Response 33) The responsibilities of a shipper under this rule are not affected by the type of shipping arrangement, *e.g.*, an FOB contract, and nothing in this rule specifies which party assumes the risk of loss.

(Comment 34) One comment asked whether the term "other persons" engaged in transportation might include governmental customs agencies that might withhold or load products during the agencies' custom processing operations for more time than considered to be usual in transport to their final destination. The commenter expresses concern that such a delay might potentially create food safety issues.

(Response 34) The 2005 SFTA authorizes us by regulation to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Generally, governmental customs officials are not engaged in food transportation operations and typically would not be subject to this rulemaking. Their role in inspecting food does not bring them within the scope of what this rule is intended to cover.

(Comment 35) A few comments asked us to address responsibility under this rule in a few situations involving international shipments into the United States. One comment, for example, asked if a rail bulk container travels from Canada to a U.S. rail yard and then is transferred to a new train, is the person or entity that initiated the shipment in Canada the shipper, or is the shipper the person that transferred the bulk container at the U.S. rail yard for further transport in the United States? Another comment asks us to identify the carrier for a closed container that is shipped into the United States by ocean-going vessel and then is transferred, unopened, at the U.S. port of entry onto a truck. Finally, one comment asks us who would be held responsible under this rule if a refrigerated container is shipped from China to the United States via ocean-going vessel and then is transferred, unopened, at the U.S. port of entry onto a truck, and upon receipt, the U.S. receiver discovers evidence of temperature abuse.

(Response 35) In the first example, the shipper for any segment of transportation of the bulk container, *e.g.*, the Canada to U.S. rail segment and also the rail segment originating in the United States, is the person who arranges for that segment of the transportation of the food by a carrier. The shipper may be the same person throughout the transit of the container if a single person arranges for all segments of its transport. In the second instance, the carrier is the person who physically moves the food from the point it becomes subject to this rule, *i.e.*, at the origination of the truck segment in the United States. With respect to the third example, the matter of (legal) responsibility will depend on whether it can be established which actor(s) (*i.e.*, the shipper, loader, and/or carrier) failed to comply with the applicable requirements of § 1.908, and whether this non-compliance contributed to the food becoming unsafe as a result of the failure to provide temperature control. At any rate, whenever it is discovered that the food may have experienced a material failure of temperature control or other conditions that could render the food unsafe, the provision in § 1.908(a)(6) applies and the food shall not be sold or otherwise distributed until it is determined that the temperature deviation or other condition did not render the food unsafe, which may involve communication among the persons subject to this rule. The responsibilities of persons subject to this rule are discussed in our response to Comment 129.

(Comment 36) One comment asks us to consider situations that include several different transportation legs in determining how parties are defined, or whether specific responsibilities assigned on the basis of the roles the persons involved in transportation operations play are even necessary. For example, corn grain is harvested and (1) taken in a semi-trailer by a farmer to the grain elevator, where it is (2) loaded in a rail car and transported to the Mississippi River, and (3) loaded in a barge for additional transport. Upon arrival, the grain is offloaded into a railcar and is then sent to a feed mill for mixing into hog feed. The comment seeks clarification on the applicability of the regulation if not all parties are subject to this rule, *e.g.*, the parties are performing a non-covered activity (*e.g.*, transport by barge or airplane) or are exempt by size.

(Response 36) In this example, the initial transportation operation would not be subject to this rule because it involves the transportation of food by a farm. In the example described in this comment, the grain elevator would be the receiver. The second segment of transit is subject to this rule because the transportation operation is by rail vehicle and the shipper, loader, carrier and receiver would be the persons who meet the definitions of these entities in this rule. These may not be separate persons, *i.e.*, the shipper and the loader may be the same person. The third segment of transit is not subject to this rule because it involves transportation by a river barge. The fourth segment of transit is subject to this rule in the same manner as the second segment.

We acknowledge that situations may occur where not all parties involved in a transportation operation are subject to this rule, *e.g.*, the shipper is a non-covered business, but the carrier is subject to this rule. In these situations, interactive requirements among covered entities established by this rule, *e.g.*, communication between shippers and carriers, would not be operative and the dialogue between the covered entities that will ensure that safe food transport requirements are understood and entities play their respective roles will not necessarily happen. This situation will disadvantage the entities that are covered businesses, especially if the shipper is not a covered entity. In situations where the shipper (or any entity) is not covered, we believe that the relevant information to ensure safe transport of food (such as appropriate temperatures for refrigeration for foods that require temperature control for safety) will be available in some form to those entities that are covered, though it may not be provided via written records which we consider ideal. Even if certain entities are not covered by this rule, all parties are subject to the general food safety requirements of the FD&C Act.

(Comment 37) A comment expressed concern with the shipper requirements because shipments originating abroad and destined for interior locations in the United States are arranged in the country of origin and the shippers in under-developed countries are not always accessible or easy to connect with, and may not be equipped to communicate with foreign companies and governments. There would be no U.S. shipper in this circumstance and it is unclear how the U.S. carrier and receiver would comply with reporting requirements related to the shipper.

(Response 37) International shipments such as those described in this comment can present difficulties for U.S. firms subject to this rule when it may be necessary to investigate the history of a shipment because, in addition to the circumstances described by the comment, a segment of the shipment, *i.e.*, ocean transport, is not subject to this rule. In circumstances where it would normally be necessary for a U.S. receiver or carrier to contact the foreign shipper under the requirements of this rule (*e.g.*, if a question arose concerning temperature control during shipment) if the shipper is not readily accessible for any reason, the carrier or receiver would have the responsibility under § 1.908(a)(6), which we discuss in Comment 129. We have added this provision to this final rule to ensure that any question relevant to whether the food may be adulterated is adequately addressed before the shipment is allowed to proceed in U.S. commerce. It is unlawful under section 301(a) of the FD&C Act (21 U.S.C. 331(a)) to introduce or deliver for introduction into interstate commerce any food that is adulterated. Further, even in cases where there is a foreign shipper, that shipper may be working in conjunction with a U.S. freight broker that could be contacted in its place to evaluate whether the food is unsafe. Moreover, if the freight broker has arranged the U.S. land-based transportation leg of the foreign shipment, the broker is the legally responsible "shipper" for purposes of the rule and therefore subject to the applicable requirements of § 1.908, including the requirement to specify to the carrier the conditions necessary to ensure the safe transport of the food. We also refer readers to our response to Comment 9.

(Comment 38) One comment states that this rule should also apply to entities that transfer a product from one mode of transportation to another (trans-loaders). It is common, particularly for feed ingredients, to have the cargo trans-loaded from a railcar to a truck. The comment recommends that FDA clarify the situations in which trans-loaders are to be considered shippers, carriers, or receivers because a trans-loader may be a separate (sub-contracted) entity.

(Response 38) An entity that only transfers food cargo from one mode of transportation to another, *e.g.*, from a railcar to a truck, would be subject to this rule as a receiver of food arriving by rail vehicle and as a loader of food onto trucks. The entity would not be considered to be a shipper if it simply holds the food pending truck transport and does not arrange for its transport by the trucking firm. The entity may also be subject to other FDA requirements that address the operation of its facility, *e.g.*, the preventive controls rules for human or animal food.

(Comment 39) One comment asks who acts as the shipper when a single container is shipped using multiple modes of transportation. A container, for example, may start its transit on a truck and then be transferred to a rail car and remain sealed until it reaches its final destination. The comment states that in such instances, the entity that initiated the shipment initially should be considered the "shipper" throughout the voyage and not an entity that transfers the container between conveyances. The comment states that if the second entity were considered to be the shipper, it might have to open the container to inspect it for cleanliness before the container continues in transit, which could impact the safety of the shipment because this would mean breaking the container's seal.

(Response 39) Under this rule, the shipper is the person who arranges for the transportation of food by the carrier. If, in the example given in this comment, a single person arranges for the shipment of the food via multiple modes of transportation, that person is the shipper throughout all stages of transport. The commenter's interpretation, that if another person becomes a subsequent shipper of a sealed container, that person would have to open the container and inspect it before shipment, is incorrect. Nothing in this rule would require the second shipper to open and inspect the sealed container.

1.900(b)

We are adding text for clarity to § 1.900(b)(2) to specify that "food that is imported for future export" specifically refers to articles of food that are subject to the provisions of section 801(d)(3) of the FD&C Act (21 U.S.C. 381(d)(3)). The added text gives definitive clarity to inform regulated entities that, when we refer to "food" that lawfully can be "imported for export," "food" means "a food additive, color additive, or dietary supplement" as specified by section 801(d)(3) of the FD&C Act.

(Comment 40) We received a comment asking us to clarify what actions food transporters must take to assure compliance when their food product is intended exclusively for export markets. Another comment states that many commodities intended for export are shipped in standard ocean containers (known in the industry as forty-foot equivalent units (FEUs) and twenty-foot equivalent units (TEUs)), which are owned or leased by steamship lines. This means that the shipper, carrier, and receiver, as identified in the proposed rule, do not own the ocean-going container, which often travels on a truck or rail chassis before reaching a U.S. port for export. The comment asserts that this complicates the relationships and documentation required in the proposed rule between the shipper and the container holder for exports.

(Response 40) The 2005 SFTA states that we must, by regulation, require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated. Further, the statute defines "transportation" as any movement in commerce by motor vehicle or rail vehicle. Thus, persons engaged in the transportation of food that is intended for export are subject to all applicable requirements of this rule when the food is in transit by motor vehicle or rail vehicle to the land-based U.S. border point of export or a port facility. For example, the loader for a truck transportation segment moving the food to a vessel port facility is subject to the rule because it is loading a motor vehicle. The loader for the trans-oceanic ship transport segment is not subject to the rule because the rule does not cover transportation operations for water borne transportation. However, the operations of the second loader are still subject to section 402(a)(4) of the FD&C Act, which prohibits the holding of food under insanitary conditions whereby it may be rendered injurious to health or may become contaminated with filth.

We recognize that under typical practices in the industry, ocean containers are likely to be inspected and otherwise prepared for transportation by the person who loads the container, *e.g.,* the shipper or loader, not by the owner or supplier of the container. As we discuss in our response to Comment 53, this rule does not place any requirements upon the owner or supplier of the container whether foreign or domestic, in circumstances where they are not a shipper, loader, or carrier, and thus we do not anticipate that there will be relational or documentation issues for shippers to address with such equipment owners as a result of this rule.

(Comment 41) Another comment asks us to include an exemption for human and animal food originating in the United States but bound for export from the requirements of this rule. The comment notes that the proposed rule would not apply to transportation operations for food that is imported but is not "consumed or distributed" in the United States because it is exclusively destined for subsequent export. The comment states that food that originates in the United States and is bound for export travels by vehicle or rail car to reach U.S. ports of exit and, like food that is transshipped through the United States to another country or food that is imported for export, it is neither consumed nor distributed until it reaches foreign soil. The comment therefore recommends that we exempt food that originates in the United States, but that is bound for export, from this rule by including under § 1.900(b) the provision: "Human and animal food that moves under Customs and Border Protection (CBP) export reporting procedures including Automated Export System (AES) and is therefore neither consumed nor distributed in the United States." The comment asserts that requiring that the shipments of the food comply with CBP export reporting and documentation procedures ensures that cargo bound for export will not be diverted into the U.S. food supply for domestic consumption.

(Response 41) We decline to exempt persons engaged in the transportation of human and animal food originating in the United States and bound for export from the requirements of this rule, because food that originates in the United States and is bound for export is handled in a fundamentally different manner than food that is transshipped through the United States to another country, for example from Mexico for delivery to Canada, or food that is imported for future export in accordance with section 801(d)(3) of the FD&C Act, and that is neither consumed nor distributed in the United States. In the cases of import for export and transshipment, legally enforceable mechanisms exist that ensure that the food will not be diverted for consumption or distribution in the United States.

With respect to food that is transshipped through the United States to another country, CBP regulations in 19 CFR 18.10, "Kinds of Entry," list the various entries and withdrawals that may be made for merchandise transported in bond. One kind of entry is the transportation and exportation (T&E) entry. A party that transships merchandise in bond through the United States must submit T&E documentation with the CBP and the CBP supervises the shipment of the merchandise through the United States, as well as the intact export of the goods to foreign destinations.

Similarly, under section 801(d)(3) of the FD&C Act, parties which import certain articles that are intended exclusively for further processing or incorporation into another product and for subsequent, mandatory export because the articles cannot be distributed or used in the United States must provide FDA with certain information at the time of initial importation. These articles include food subject to this rule, specifically, food additives, color additives and dietary supplements. These parties must provide, among other things, a statement that confirms their intent to further process such articles or incorporate such articles into a product for purposes of subsequent export, and must provide us with the identities of the entities in the chain of possession of the imported articles while the articles are in the United States. Importers also must provide us with certificates of analysis, as necessary, to identify the article of food. In addition, at the time of initial importation and before delivery to the importer, initial owner, or consignee, a bond must be executed providing for liquidated damages in the event of default, in accordance with CBP requirements. The initial owner or consignee of the article also must maintain records of the use and/or destruction of such imports and must submit the records or a report to FDA upon request. The initial owner or consignee also must destroy any article or portion thereof that is not used in an exported product.

The AES system, on the other hand, collects Electronic Export Information (EEI), formerly known as Shipper's Export Declaration (or any successor document) from persons exporting goods from the United States, Puerto Rico, or the U.S. Virgin Islands; between Puerto Rico and the United States; and to the U.S. Virgin Islands from the United States or Puerto Rico. AES is the central point through which export shipment data required by multiple Federal Agencies is filed electronically with CBP and is operational at all ports and for all methods of transportation. It was designed to assure compliance with and enforcement of various export laws, improve trade statistics, reduce duplicate reporting to multiple agencies, and improve customer service.

However, AES is not specifically designed to function as a legally enforceable mechanism to ensure that food bound for export is not diverted into the domestic supply chain and consumed in the United States. The AES system does not become operative until food arrives at a point of export. Therefore, if a shipper states that any given food shipment that originates in the United States is destined for export and transports the food without complying with the requirements of this rule, but subsequently decides to divert the food for purposes of domestic consumption or distribution, neither we nor the CBP would have any way of knowing that the food had been diverted for domestic consumption, perhaps after being transported under insanitary conditions. In addition, unlike food transshipped through the United States and food imported exclusively for subsequent export, food that originates in the United States and is intended for export, whether it is diverted for domestic consumption or is actually exported, is not transported under a bond. Accordingly, we do not agree that a basis comparable to that for food transshipped through the U.S., or food imported for export, exists for exempting persons engaged in the transportation of human and animal food that originates in the United States but is bound for export from the requirements of this rule as suggested by this comment.

(Comment 42) One comment states that, when cargo is deemed to be adulterated, one of the primary salvage markets may be destinations outside of the United States. The comment observes that this rule appears not to apply to food outside of the United States and argues that, if that is the case, we should clarify that it should not apply to food that is shipped outside of the United States to a destination that was not the original, intended primary market.

(Response 42) If the product has already been offered for sale in the United States and is found to be adulterated, it cannot be legally exported for sale in markets outside the United States. (See *United States* v. *Kanasco, Ltd.*, 123 F.3d 209 (4th Cir. 1997) (although this case involved drug products and not food, it stands for the principle that, if product is adulterated, it cannot be legally offered for sale outside the United States).) The owner of the product can pursue other lawful options, such as reconditioning the product or diverting the product to nonfood uses. If, however, the food has not been offered for sale in the United States and otherwise meets the requirements of section 801(e)(1) of the FD&C Act, it can be shipped abroad and would not be subject to the adulterated food provisions of the FD&C Act and therefore would not be subject to this rule.

(Comment 43) A comment requests that we address the safe disposal of contaminated foods from a rejected delivery and the sanitization of trailers carrying such cargo. The comment states that when a delivery is rejected, the responsibility for and costs associated with safely disposing of the shipment is often placed on truckers, in some cases with little or no instructions from the shipper. Consequently, according to the comment, drivers who need to dispose of contaminated cargo sometimes simply dump it, give it away to the public, or sell it. The comment states that FDA should explore, in this or a separate rulemaking, the development of rules governing such rejections. The comment further suggests that we should address when rule violations can serve as the basis for the rejection of a delivery and/or a cargo insurance claim, acceptable methods of disposing of contaminated food products after rejection, and the apportionment of disposal costs among parties involved in the transportation of rejected cargoes.

(Response 43) This rule addresses the sanitary transportation of human and animal food to prevent practices that may create food safety risks. We recognize the burdens and uncertainties that may arise when a load is rejected. However, the basis on which a load may be rejected, and the disposition of and costs associated with the disposal of rejected loads of food, are beyond the scope of this rule. We do not agree that we should explore the development of rules to govern rejections and/or cargo insurance claims, or rejected product disposal issues, because they often involve purely economic considerations about food shipments, which do not fall within our jurisdiction. Also, issues of liability are similarly subject to Federal laws that we do not have the authority to administer. We note, however, that if a food shipment is rejected because it is adulterated, the person responsible for that food cannot distribute or offer it for sale. Further, the carrier of a rejected food shipment must ensure that the motor or rail vehicle used to transport the rejected load complies with the vehicle and equipment provisions of § 1.906 before it is used again to transport food.

B. How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act? (§ 1.902)

The only change we made in the proposed provisions in § 1.902(a) and (b), which specify that the criteria and definitions in part 1, subpart O apply in determining whether food is adulterated within the meaning of section 402(i) of the FD&C Act and that failure to comply with the requirements of part 1, subpart O is a prohibited act, was to add "loaders" to the list of covered entities in both paragraphs.

(Comment 44) One comment asks us to replace the term "in compliance" throughout the final rule with the term "in conformance."

(Response 44) We decline this request. We have used the phrase "in compliance" in § 1.902(a) of this rule consistent with the language of section 7202(a) of the 2005 SFTA, which amends the FD&C Act by adding section 416 to the FD&C Act to provide that a food shall be deemed to be adulterated "[i]f it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416."

(Comment 45) Several comments express concern about food being considered adulterated under this rule simply because of the failure of a carrier to adhere to a shipper's specified conditions during transport, such as maintaining a specified temperature, regardless of whether the food is actually unsafe. In particular, these comments speak to concerns about the impact the rule, as proposed, would have on the cargo claims process governed by the "Carmack Amendment" found in 49 U.S.C. 14706. Under this provision of Federal law, a shipper or receiver seeking to recover money for cargo loss or damage from a carrier must show that the cargo is actually lost or damaged. The mere possibility of damage through "potential" exposure is not sufficient to prove an actual loss. One comment states that this rule is problematic because it directly links failure to adhere to shipper-specified conditions for transportation with adulteration of, or damage to, food products during transport. According to this comment, the operation of this rule would mean that a claimant would no longer be required to prove that a shipment of food is actually damaged, but rather would only be required to prove the shipment was not maintained in accordance with a shipper's specified condition. One comment also states that this rule should clearly state in § 1.902 that "Variance from the requirements of this rule does not create a per se presumption of adulteration, and that the provisions of the Carmack Amendment, 49 U.S.C. 14706, still apply in determining liability of the parties regarding loss or damage to cargo."

(Response 45) We decline to make the specific change requested, but we have made other revisions to this rule that address the commenter's concerns. We have revised the provisions of this rule, for example, that address instances in which a carrier might not meet a shipper's specifications for temperature control during transportation. An inconsequential failure by a carrier to meet the shipper's temperature control specifications will not necessarily create a per se presumption that the affected food has become adulterated. However, as we discuss in our response to Comment 129, under this rule, in § 1.908(a)(6), if a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the person must take appropriate action to ensure that the food is not sold or otherwise distributed, unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. Failure to take such action may render the food adulterated.

We also have revised this rule in §§ 1.906 and 1.908, as we discuss in our response to Comment 89, to clearly state that the requirements for transportation equipment and transportation operations are intended to prevent food from becoming unsafe during transportation. This revision, in addition to others, makes it clear that under this rule we will apply section 402 of the FD&C Act, as it addresses food safety, to determine whether food has become adulterated during transport. Persons engaged in transportation operations should not expect that we will apply a different standard or different criteria for evaluating compliance with this rule. Therefore, we do not anticipate that this rule will have a significant impact on the cargo claims process.

(Comment 46) Some comments state that there are other common occurrences that they believe could unnecessarily result in a presumption of adulteration under the proposed rule. These commenters express concern that the proposed rule can be interpreted broadly enough to create potential issues if broken seals or evidence of tampering create a presumption of adulteration, absent any evidence of actual threats to the public health.

(Response 46) We have made revisions to this rule that address the concerns of these comments. As we stated in our response to the previous comment, when assessing transportation equipment and transportation operations, we will apply the food safety provisions of section 402 of the FD&C Act as the standard for determining whether food has become adulterated during transport. Persons engaged in transportation operations should not expect that we will apply a different standard or different criteria for evaluating compliance with this rule. A broken cargo seal or any evidence of food cargo tampering would not necessarily create a per se presumption of adulteration. However, we advise persons engaged in transportation operations that, if such situations should arise, they should carefully evaluate the facts and circumstances of each incident, on a case-by-case basis, to determine whether the safety of the food cargo may have been compromised.

(Comment 47) Some comments asked that we clarify, in certain particulars, the interpretation of "conditions not in compliance" in section 402(i) in the FD&C Act, the statutory adulteration provision added to the FD&C Act by the 2005 SFTA. Under that provision, a food is adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations issued under section 416 of the FD&C Act, *i.e.*, this final rule. Some of these comments expressed concern that the application of this provision would lead to food being deemed adulterated by regulatory authorities in the absence of physical conditions indicating a food safety risk. One comment stated that non-compliance with the recordkeeping provisions of this final rule alone should not be a basis for deeming food to be adulterated, assuming the records and documentation of the firm do not indicate a systematic and continued failure of a firm to implement sanitary transportation practices. A comment also asked us to recognize that under this rule, an enforcement authority will retain the discretion to consider the specific circumstances in each situation, *e.g.*, if there are only minor deviations from the requirements of this rule, in determining whether food is adulterated.

(Response 47) Under section 402(i) of the FD&C Act, "a food shall be deemed adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416." Section 416(b) of the FD&C Act mandates that the Secretary create regulations requiring that food carriers use sanitary transportation practices. Section 416(c)(1)(E) of the FD&C Act states "the regulations under section (b) shall—(1) prescribe such practices as the Secretary determines to be appropriate relating to— . . . (E) recordkeeping . . ." The way that the statute is structured implies that lack of or incomplete records in section 416(c)(1)(E) of the FD&C Act would lead to the food being adulterated under section 402(i) of the FD&C Act. The establishment of records requirements under this rule is consistent with the statutory purpose of the 2005 SFTA. It is clear from the statute and the legislative history that Congress intended recordkeeping to be one of the requirements for maintaining sanitary food transportation practices (See section 416 of the FD&C Act and S. Rep. No. 109–120, at 46 (2005) (Ref. 25)).

Furthermore, the Senate report (S. Rep. No. 109–120, at 46 (2005)) (Ref 25) expresses Congress' intention to grant FDA authority to deem food adulterated on recordkeeping grounds. That report states that SFTA "would amend section 402 of the Federal Food, Drug, and Cosmetic Act . . . to provide that food is adulterated if transported in violation of safe transportation practices prescribed in the new section 416 of the FD&C Act."

In the seafood HACCP final rule (60 FR 65096 at 65100) we noted that in *National Confectioners Association* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978), the courts upheld FDA's authority to issue regulations under section 402(a)(4) of the FD&C Act that included recordkeeping requirements, when challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but the records were deficient.

Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the FD&C Act. Citing *Toilet Goods Association* v. *Gardner,* 387 U.S. 158 (1967), the court rejected this argument and held that the primary consideration was whether the statutory scheme as a whole, not just section 402(a)(4) of the FD&C Act, justified the Agency's regulations. (See *Nat'l Confectioners Ass'n,* 569 F.2d 690 at 693.) The court pointed out that this consideration involved an inquiry into practicalities as well as statutory purpose, *i.e.,* enforcement problems encountered by FDA and the need for various forms of supervision in order to accomplish the goals of the FD&C Act. (Id.)

Thus, the necessary conditions for compliance with these regulations encompass all of the requirements in this final rule, including those that may not appear to directly affect the safety of the food, such as training and records. The SFTA of 2005 does not differentiate between physical conditions indicating food safety risk and requirements, such as training and recordkeeping.

However, we recognize the concerns expressed by these comments and do not believe that the SFTA of 2005 changes the way we enforce our regulations. Before initiating enforcement action, we will consider all circumstances surrounding the deviation(s), *e.g.,* the nature of the deviation, from these regulations as we have in the application of other preventive control-type regulations, such as the seafood HACCP regulation and the Juice HACCP regulation.

(Comment 48) One comment states that the rule does not address the obligations of carriers if shelf stable food is compromised during transit or while on a dock or being loaded onto a trailer. The comment states that when a shipment is damaged in transit, or during loading or unloading, the carrier will frequently transport the shipment of damaged goods to a location of the shipper's choice. The commenter asks us, if the carrier is only qualified to handle shelf stable food, can the carrier continue to handle the shelf stable food with compromised packaging? The comment also asks whether the carrier would be required to hire another carrier who has chosen to comply with the record keeping and training requirements of the proposed rule to handle the return of such shipments.

(Response 48) We would have no concerns about the carrier transporting the damaged goods to a location specified by the shipper because, under § 1.908(a)(6), an evaluation must be performed before further distribution to determine whether the food has been rendered unsafe.

C. What definitions apply to this subpart? (§ 1.904)

We proposed to establish several definitions in § 1.904. In table 6, we describe revisions to the proposed definitions and following the table we respond to comments related to these provisions. We did not make changes to the definitions of adequate, animal food, bulk vehicle, cross-contact, food not completely enclosed by a container, pest, transportation, and vehicle.

TABLE 6—§ 1.904 WHAT DEFINITIONS APPLY TO THIS SUBPART?

Definition	Revision
Carrier	Revised definition to specify that carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States.
Farm	Applied farm definition given in § 1.227 (21 CFR 1.227).
Food	Removed the term because it is already defined in section 201 of the FD&C Act.
Full-time equivalent employee	A new definition. Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number.
Microorganisms	Removed the term because not needed with revised provisions in §§ 1.906 and 1.908.
Loader	A new definition. Loader means a person that loads food onto a motor or rail vehicle during transportation operations.
Non-Covered Business	Specified the limit of $500,000 as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011. Added "loader" to list of potential non-covered businesses.
Person	Removed the term because it is already defined in section 201.
Receiver	Revised definition to specify that receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.
Shelf Stable Food	Removed the definition, not needed for revised definition of "transportation operations".
Shipper	Revised to specify that shipper means a person who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. Provided examples of shipper, such as the manufacturer or a freight broker.
Small Business	Specified the limit of $27,500,000 annual receipts. Specified that employee limit is fewer than 500 full-time equivalent employees.
Time/Temperature Control for Safety (TCS) Food.	Removed the definition, not relevant to revised temperature control provisions.
Transportation	Revised to specify that transportation means any movement of food by motor vehicle or rail vehicle in commerce within the United States.
Transportation Equipment	Removed "other than vehicles" for clarity.

TABLE 6—§ 1.904 WHAT DEFINITIONS APPLY TO THIS SUBPART?—Continued

Definition	Revision
Transportation Operation	Removed "solely" and "shelf stable" to specify that transportation operations do not include activities on a food completely enclosed by a container except a food that requires temperature control for safety. Added that transportation operations do not include any activities associated with the transportation of "food contact substances as defined in section 409(h)(6) of the FD&C Act," "human food byproducts transported for use as animal food without further processing," or live food animals "except molluscan shellfish". Removed "for raw agricultural commodities" to specify that transportation operations do not include any transportation activities performed by a farm.

1. Adequate

We proposed to define the term "adequate" to mean that which is needed to accomplish the intended purpose in keeping with good public health practice. We are finalizing this definition as proposed.

(Comment 49) One comment states that the term "adequate" is not suitable for a rule intended to achieve compliance with best transportation practices focused on reducing the risks of the adulteration of food products. The comment suggests that instead we should use the term "to guarantee," which the comment defines as meaning "to ensure and protect from any risk or need," to avoid ambiguity that might cause confusion and result in public health hazards.

(Response 49) We decline this request. The term "adequate" is a long-standing term that we defined in its current form when we first established Current Good Manufacturing Practices (cGMP) requirements for manufacturing, packing and holding food in 1969 (see 34 FR 6977 at 6978, "'Adequate' means that which is needed to accomplish the intended purpose in keeping with good public health practice."). The requirements established in this rule address broadly applicable procedures and practices and our use of the term "adequate" is intended to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements in a way that is most suitable for their practices. We are not aware that the term has caused confusion in its use with the cGMPs and the comment does not provide any examples of how our use of the term "adequate" may create confusion that might result in public health hazards.

2. Animal Food

We proposed to define the term "animal food" to mean food for animals other than man, including pet food, animal feed, and associated raw materials and ingredients. We are finalizing this definition as proposed.

(Comment 50) A few comments state that raw materials should not be included in this definition because processing these materials into feed ingredients and finished animal food products after they have been transported to processing facilities removes many, if not all, of the hazards that may be associated with the transportation of the raw materials. One of the comments also notes that the Association of American Feed Control Officials (AAFCO) Model Regulations exempt raw materials (such as meat scraps) from regulation because they are not suitable for use in animal feed without further processing.

(Response 50) We decline to change the definition of animal food. While the transportation of raw materials for animal feed manufacture may not require the same degree of sanitary control as the transport of finished animal feed, there may be circumstances in which processing the raw materials may not remove all health hazards, *e.g.*, fertilizer residue from a prior cargo hauled in a vehicle, that might be caused by the insanitary transportation of the raw materials. We have added provisions to § 1.908(a)(3) of this final rule to provide sufficient flexibility to allow persons engaged in the transport of raw materials, feed ingredients, or finished animal food to use sanitary transportation practices that are appropriate for their circumstances.

3. Bulk Vehicle

We proposed to define the term "bulk vehicle" to mean a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the interior surfaces of the vehicle. We are finalizing this definition as proposed.

(Comment 51) One comment asks us to add terms such as "gondola" to the examples included in this definition in the interests of clarity.

(Response 51) We decline to change the definition based on this request. We are using the definition of "bulk vehicle" in this rule exactly as it appears in the 2005 SFTA and as incorporated into section 416 of the FD&C Act. However, we note that the list of examples included in the definition is not intended to be comprehensive or all inclusive with respect to the types of vehicles that are bulk vehicles. We define the term to include "any other vehicles in which food is shipped in bulk, with the food coming into direct contact with the vehicle."

(Comment 52) Some comments state that in several respects, our definition of bulk vehicle is overly broad in scope. According to one commenter, the term "hopper bin," for example, can be inferred to mean a grain hopper bottom storage bin that is part of a storage facility, and not a piece of transportation equipment. The comment requests that we delete the term "hopper bin" from this definition. Another comment asks us to explicitly exclude vehicles used to transport fruit and vegetable RACs from the definition because many RACs are thermally processed with a kill step or are cooked by the consumer before being consumed.

(Response 52) We decline these requests. A hopper bin constructed as part of a facility and used for storage would not be considered transportation equipment and therefore would not be subject to this rule. A hopper bin on a truck or other conveyance subject to this rule, however, is a piece of transportation equipment and therefore is subject to this rule. We also note that while some RACs that are transported in a bulk vehicle may undergo a kill step process or cooking before being consumed, there may be circumstances in which controls, *e.g.*, the cleaning of a vehicle that was last used to haul a nonfood item, are necessary to ensure the sanitary transportation of certain types of RACs. We have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transport of food intended for further processing to employ sanitary transportation practices that are appropriate for their circumstances.

4. Carrier

We proposed to define the term "carrier" to mean a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. The definition also specified that the carrier is responsible for all functions assigned to a carrier in this subpart even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm, and that a carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons as defined in this subpart. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision to that section about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of "carrier," "shipper" and "receiver". We are finalizing the definition for "carrier" to mean a person who physically moves food in commerce and clarifying that a carrier does not include any person who transports food while operating as a parcel delivery service. We explain these changes in the responses to the next 3 comments.

(Comment 53) Some comments oppose defining the term "carrier" to mean a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food. These commenters express concern that this definition would result in the inappropriate and unworkable application of this rule's requirements to railroad operators for the following reasons.

- Railroad operators in many cases do not own or lease the railcars they transport, are not responsible for their storage when they are stored in private facilities, and exercise no control over the cars other than to inspect them for mechanical soundness during the transportation process.
- The shipper or loader is generally responsible for inspecting a railcar to ensure that it is suitable for the particular food cargo, regardless of who owns the car.
- Railroad operators do not have the ability to ensure that the shipper's sanitary and temperature control requirements are met before or during transportation when, as is common in freight railroad transport, other parties, *e.g.*, the shipper, assume the responsibility for preparing the railcars for loading, maintain their operating conditions during transportation, and deliver the loaded car to the railroad operator for transport.
- Railroad operators generally do not clean the cars they provide and do not maintain documented cleaning procedures.
- The use of railcars in interchange service, in which railroads convey freight cars from other companies over their lines would likely mean that the railroad operator would not be able to provide information about the identity of a bulk vehicle's previous cargoes and its most recent cleaning if requested by the shipper.

The commenters note that for the stated reasons, railroad operators cannot meet requirements of this rule assigned to carriers under proposed §§ 1.906 and 1.908.

These comments also contrast rail carrier and motor carrier food transportation operations, noting that motor carriers generally own the vehicles they provide for transport and are directly involved in transportation operations, such as the loading and unloading of the trailers that they haul, and therefore can comply with requirements assigned to the carrier in §§ 1.906 and 1.908 of the proposed rule.

Finally, one comment asks us to establish separate definitions for motor and rail carriers which would assign appropriate responsibilities for each of the two distinct types of carriers. Another comment asks us to establish a definition specific to railroad carriers in this final rule, which would simply define a "railroad carrier" as a person providing railroad transportation services.

(Response 53) We carefully considered these comments and we agree that our proposed definition of the term "carrier," when combined with the structure of the proposed requirements at § 1.908, which detail the required interrelationships between carriers, shippers and receivers, would establish requirements that some persons subject to the definition, *e.g.*, some railroad operators, typically cannot meet, and which are currently performed by other parties, *e.g.*, the shipper. Because it is our intent to pattern this rule on existing industry best practices, we agree that we should not reassign responsibilities for activities that affect food sanitation during transportation in this final rule in a manner that is so fundamentally divergent from current practice.

We recognize that, in practice, the person who assumes responsibility for functions assigned to a carrier under § 1.908 of the proposed rule is identified by mutual agreement between the shipper and that person, *e.g.*, the trucking firm, the railroad operator, the railcar management firm, or that the shipper may itself assume the responsibility. We also recognize, as one of the comments mentions, that railroad operators typically do not assume these responsibilities. Nonetheless, we are aware that, though not common in the rail transportation of food, some railroad operators do perform functions that affect the sanitary condition of a railcar during transportation of the food, *e.g.*, monitor the temperature of the car. However, we do not agree that a separate definition for rail carriers is the appropriate solution, because some rail carriers, in fact, perform functions that are typically performed by motor carriers. Rather, we have concluded that the appropriate solution with regard to the definition and the overall carrier regulatory requirements is: (1) A simplified definition of carrier that ties it to the movement of the food; (2) removal from the carrier definition of any assignment of duties; and (3) a default assignment of responsibility to the shipper for the activities assigned to carriers in the proposed rule, unless a written contract between the shipper and carrier assigns them to the carrier (or another party covered by this regulation, as may be the case). We are aware that contracts for services that impact food safety (*e.g.*, monitoring temperatures, cleaning vehicles) generally are in place when rail or motor carriers provide such services. Therefore, linking responsibility for the carrier to perform such functions to the existence of a contract with the shipper, in which such functions are specified, seems appropriate and consistent with current industry best practice.

For these reasons, we have revised the definition of carrier to mean a person who physically moves food by rail or motor vehicle in commerce in the United States. We have removed from the definition the proposed sentence that assigned duties to the carrier, because of the consequences of such assignment, especially relative to rail carriers, as discussed in this document, and because, upon further consideration, we view such language to be inappropriate for a definition. We have also removed from the definition the proposed sentence that stated that a carrier may also be a receiver or a shipper if the person also performs the functions of those respective persons. While we affirm that this statement is valid, we have consolidated this and similar statements in the proposed definitions of shippers and receivers in the regulatory text at § 1.908(a)(1).

(Comment 54) A few comments urge us to consider that home grocery delivery services may originate from locations other than food establishments, such as a distribution center. According to the comments, the transportation of the food from distribution center to the consumer would be subject to the proposed requirements for a carrier. The commenters note, however, that there would be no receiver in this scenario because the definition of receiver explicitly excludes consumers. The comments ask us to revise the final rule so that it does not impose unnecessary regulatory burdens for home grocery deliveries originating at locations other than food establishments.

(Response 54) Home grocery delivery operations at food distribution centers are generally permitted by States as retail establishments and, therefore, would be included in a waiver of certain transportation operations performed by such retail food establishments. We stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to retail food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment. As we stated in section III.E., we intend to publish a waiver in the **Federal Register** addressing this class of persons prior to the compliance date of this final rule.

(Comment 55) A participant in one of the public meetings we held on the proposed rule asked whether this rule applies to food shipped by the U.S. Postal Service or by private small parcel carriers. One submitted comment states that the impact of the rule would be significant and costly if it is applied to small-parcel common carriers, and therefore asks us to affirmatively state that small-parcel common carriers will be excluded from the definition of "carrier." The comment notes that small-parcel common carriers handle millions of packages per day containing a broad range of goods, including clothing, shoes, food products, electronics products, and books. The comment asserts that requiring these carriers to understand the unique shipping requirements for every product that they transport would be unduly burdensome and nearly impossible to accomplish. The comment further argues that if FDA requires that small-parcel common carriers meet the requirements imposed on dedicated food carriers, some common parcel carriers, especially large-scale common carriers, will respond by simply excluding all food shipments from their operations. According to the commenter, this result would likely reduce the availability of some of the most cost-effective transportation channels for certain food shippers, even where there have been no demonstrated food safety risks associated with their food product delivery operations. Finally, the commenter suggests that the more appropriate way to ensure food safety under these circumstances would be to require the shipper of any small parcel to ensure that the selected method of transportation is appropriate for the food product at issue.

(Response 55) We agree that it is not appropriate to subject the operations of the U. S. Postal Service or private delivery services delivering parcels to consumers to this rule, given that these carriers transport a broad range of items and do not offer transportation services tailored to the transportation of food products. We, therefore, have added a provision to the definition of the term "carrier" in § 1.904 of this final rule stating that the term does not include any person who transports food while operating as a parcel delivery service. Our expectation is that the person shipping the package would ensure that the selected method and circumstances of transportation are appropriate for the food product at issue, including food that is delivered by small-parcel common carriers.

5. Cross-Contact

We proposed to define the term "cross-contact" to mean the unintentional incorporation of a food allergen as defined in section 201(qq) of the FD&C Act into food, except animal food. We did not receive any comments on this definition and are finalizing it as proposed.

6. Farm

We proposed to define the term "farm" to mean a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The proposed definition of "farm" included facilities that pack or hold food, regardless of whether all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership. We are revising the definition of "farm" in this rule to be consistent with the definition of "farm" used in other FSMA rulemakings. We discuss our considerations of the comments we received on the definition of "farm" in the response to Comment 55 and, additionally, in our response to Comment 8.

(Comment 56) Several comments that address provisions of the proposed definition of "farm" suggest that the definition include terms such as a "facility," or an "establishment," or a "place." Other comments suggest that the definition should include consideration of the locations and the numbers of the structures that constitute a farm.

(Response 56) As we explained in our response to Comment 8, we have revised the definition of the term "farm" in this final rule to align it with the revised definition of the term in 21 CFR 1.227, which was recently established in the FSMA preventive control for human food final rule (80 FR 55908 at 55925). The comments that we received for this rulemaking address provisions of the farm definition that have already been addressed in the rulemaking for preventive controls for human food. Therefore, there is no need for us to address these issues further in this rulemaking.

7. Food

We included the definition of the term "food" in the proposed rule just as the term is defined in section 201(f) (21 U.S.C. 321(f)) of the FD&C Act. We have deleted this definition from this final rule, however, because § 1.904 of the rule clearly states that "[t]he definitions and interpretations of terms in section 201 of the [FD&C Act] are applicable to such terms when used" in this rule. Food includes animal food and food also food subject to the FMIA, the PPIA, and the EPIA.

(Comment 57) One comment asks us to explicitly exclude food contact shipping and storage equipment from the rule's definition of "food." The comment also asks us to clarify that empty food contact shipping and storage equipment will be regulated exclusively as "transportation equipment" under this rule. Finally, the comment asks us to clarify that equipment suppliers, including food contact equipment suppliers, are not shippers, carriers or receivers of "food."

(Response 57) The definition of "food" given in section 201(f) of the FD&C Act applies to this term as used in this rule. Under section 201(f), the term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Shipping and storage equipment that is meant to contact food is not food and would be regulated exclusively as "transportation equipment" under this rule. Therefore, persons involved in the transportation of such equipment are not shippers, carriers or receivers of "food." However, the food contact surfaces of such equipment must comply with any other applicable regulations we have established, *e.g.,* food additive regulations, for any components that may migrate into food under their intended conditions of use.

(Comment 58) A few comments ask us to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act from the scope of this rule by excluding them from the definition of "food." One of the comments notes that we excluded food contact substances from the definition of "food" in the food facility registration regulations in 21 CFR 1.227(b)(4). It further states that requiring manufacturers, shippers, receivers, and carriers of food contact substances to comply with the sanitary transportation requirements would impose a significant burden with respect to the transportation of products that present a very low food safety risk and for which any risk is already effectively managed.

(Response 58) We partially agree with these comments. In the 1990 SFTA, Congress included food additives along with other substances defined in the FD&C Act in designating the scope of the regulations that it directed DOT to issue. We take this to mean that Congress recognized that food could be made unsafe as a result of insanitary food additive transportation practices. Food contact substances are "food additives" and are also "food" as defined in the FD&C Act. In the absence of language in the 2005 SFTA that explicitly excludes food contact substances from regulation as food, we would not agree with the comment's view that food contact substances should not be considered to be "food" within the meaning of this rule.

However, section 416(c)(1) of the 2005 SFTA states that we shall prescribe sanitary transportation practices that we determine to be appropriate in issuing this rule. We, therefore, are revising the definition of transportation operations to exclude food contact substances as defined in section 409(h)(6) of the FD&C Act. Factors inherent to the transportation and downstream handling of food contact substances, described in this section, would strongly support that there is little risk of food products becoming adulterated because of insanitary food contact substance transportation practices. We agree, as one comment notes, that food contact substances are protected during transportation with additional outer packaging. In addition, the pathogenic microorganisms that are deleterious to conventional foods are not known to be a risk for food contact substances. We also note that the handling and processing that these substances undergo during the manufacturing of finished food contact articles, such as curing, drying, and extrusion, often involve very high temperatures, creating conditions under which there is little possibility that any microorganisms that might be present would survive. The nature of finished food contact articles also ensures that the risk of microbial contamination is very low. We, therefore, have determined that requirements under this rulemaking for the sanitary transportation of food contact substances are not necessary.

8. Food Not Completely Enclosed by a Container

We proposed to define the term "food not completely enclosed by a container" to mean any "food that is placed into a container in such a manner that it is partially open to the surrounding environment." We stated in the proposed rule that examples of such containers would include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag, but would not include food transported in a bulk vehicles. We are finalizing this definition as proposed.

(Comment 59) One comment objects to our proposed inclusion of food packaged in vented cardboard cartons with tops as an example of "food not completely enclosed by a container." Several comments disagree that the use of vented cartons by the tree fruit industry poses a measurable risk of contamination to fruit during transportation. One comment observes that vented cardboard cartons with tops are a commonly used for cooling fruit and contribute to the maintenance of fruit quality. According to the comments, vented cartons bearing fruit are stacked on pallets before being placed in refrigerated trucks by forklifts, and they are removed the same way and without ever coming into direct contact with the trucks' interior surfaces. The comments also assert that it is rare for loads of fruit packaged this way to be transported with any other food products, further reducing the risk of cross-contamination or adulteration. Finally, the comments also assert that no evidence of any threat to food safety has emerged over the many decades that the tree fruit industry has used these types of cartons for packaging and transportation.

(Response 59) We agree that when sanitary transportation practices are followed in the transportation of tree fruit, there should be no significant risk of contamination of the product. However, we decline the request to exclude vented cardboard cartons from the definition of "food not completely enclosed by a container." The purpose of this rulemaking is to prescribe sanitary transportation practices to ensure that food does not become unsafe during transportation. We have determined that it is necessary to establish requirements related to the transportation of foods not completely enclosed by a container, including food transported in vented cardboard cartons with tops, because food, including tree fruits, packaged this way could be susceptible to environmental contamination, for example, if a vehicle used for transport is not in appropriate sanitary condition for the transportation operation.

(Comment 60) One comment states that it is unclear what we mean by a "completely enclosed container" as it relates to storage practices during loading and transportation operations. The comment asks whether this means food must be enclosed by a cardboard box or a plastic wrapped pallet, or whether food must be enclosed by a moisture impervious container such as ones made out of heavy plastic, glass or metal. The commenter states that it has seen "extreme examples of cross contamination, such as raw poultry on ice, stored above fresh produce with bloody ice falling into the produce." The commenter asks us to provide clearer language.

(Response 60) We consider a "completely enclosed container" to be one that physically separates the food from the environment and functionally protects the food from environmental contamination during transportation. We would not consider items such as pallet wrap, which have the primary purpose of facilitating the handling of pallets, to be food containers. We provided examples of such containers in the proposed rule (79 FR 7006 at 7015), *e.g.,* a metal can, a glass or plastic bottle, or a sealed bag or box.

9. Full-Time Equivalent Employee

"Full-time equivalent employee" is a new term in this rule and is used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.,* 40 hours × 52 weeks). If the result is not a whole number, round down to the next lowest whole number. We are adding this term to the rule to clarify its use in the revised definition of "small business" in this rule. The use of this term is consistent with the use of the same term in the preventive controls rules for both human and animal food.

10. Loader

We are adding the term "loader" to this rule and specifying that it means a person that loads food onto a motor car or rail vehicle used during transportation operations. We are adding this term in response to comments that indicated that there were certain functions assigned in the proposed rule that were typically performed by a segment of the transportation industry known as loaders and so we have added this function to the rule.

11. Microorganisms

We proposed to define the term "microorganisms" to mean yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and to include species that have public health significance. We proposed to define the term "undesirable microorganisms" to include those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated. We have removed this term as explained in the response to Comment 61.

(Comment 61) One comment states that although these definitions are familiar from the existing food cGMP regulations at 21 CFR part 110 (which have been revised in the preventive controls for human food final rule and are now in 21 CFR part 117, subpart B), they provide little assistance for purposes of identifying foods that can support the rapid growth of undesirable microorganisms in the absence of temperature controls. Other comments state that we should clarify that microorganisms that have only the potential to cause spoilage, without posing food safety risks, should not be excluded from these definitions of microorganisms.

(Response 61) We included a definition for the term "microorganisms" in the proposed rule that was to be applied to requirements in proposed §§ 1.906 and 1.908 that addressed measures necessary to prevent conditions that could lead to the rapid growth of undesirable microorganisms in food because of the use of insanitary transportation equipment and transportation practices. As we explained in our response to Comment 89, we have revised the language in these sections of this final rule to no longer refer to the term "undesirable microorganisms." As a result of this revision, there is no longer a need to include a definition for the term "microorganisms."

12. Non-Covered Business

We proposed to define the term "non-covered business" to mean a shipper, receiver, or carrier engaged in transportation operations that has less than $500,000 in total annual sales. We have changed the annual sales qualifier in this provision to an annual revenue qualifier because under this rule, this definition applies to firms, *e.g.,* loaders that do not sell products. In addition, to be consistent with the models used in other FSMA rulemakings (*e.g.,* the preventive controls final rules) for similar calculations, we have revised this definition to provide that the annual revenue calculation is based upon an average value for 3 years preceding the applicable calendar year, and allows for adjustment for inflation.

(Comment 62) We received a large number of comments regarding this proposed provision. Most of them oppose granting any kind of size-based exclusion. Several themes emerge from the comments that we received opposing the inclusion of a size-based exclusion in this rule. Many of the comments ask us to create a "very small" category of businesses which would be subject to fewer requirements than other firms. Some of these comments state that the proposed exclusion provision leaves the most problematic group of transporters, operators of small box trucks, uncovered by this rule, citing the findings that we discussed in the proposed rule (79 FR 7006 at 7024), of the 2007 Interstate Food Transportation Assessment Project (Ref. 6). Some comments expressed the view that that all members of the food supply chain, regardless of size, must share responsibility in ensuring food safety. Some comments criticize the proposed exclusion for lacking a statutory basis, for not being risk-based, or for lacking merit and being unnecessary. One comment opposes the proposed exclusion on the grounds that we have failed to explain why the proposed rule's requirements would be prohibitive for those firms capable of qualifying for the exemption. Other commenters state that we should not grant any exclusions because the proposed requirements are similar to food cGMPs, which we impose on almost all food processors.

(Response 62) We articulated our reasons in the proposed rule (79 FR 7006 at 7014) for excluding certain businesses, *i.e.,* a "non-covered business," from the requirements of this rule. We stated that we want to treat firms subject to this rule comparably to those firms that are subject to the FSMA preventive controls rules. We also stated that we want to treat carriers, who are not subject to the preventive controls rules, in the same manner as we treat other firms engaged in food transportation operations that are also subject to this rule. We chose to do this by providing an exclusion for these businesses, recognizing that their transportation operations are also, and will continue to be, covered under the adulteration provisions and other applicable provisions of the FD&C Act and all of our applicable implementing regulations. In light of this, and recognizing businesses that would qualify for this size-based exclusion would have fewer resources to dedicate to complying with this rule, we chose to exclude these businesses from this rule rather than create a separate category of very small business that would be subject to fewer requirements than other firms. We estimate that the removal from coverage of entities less than $500,000 in average annual revenues, as we have set out in this final rule, would result in only about 5 percent of food shipments not being covered by this rule. The risk of any foodborne outbreak associated with this narrow range of shipments therefore is, thus, necessarily limited in scope. Notwithstanding the information on small box trucks contained in the 2007 Interstate Food Transportation Assessment Project, we are not aware of data that supports the assertion of some comments that shipments by the smallest firms, *i.e.,* those that would meet the definition of a non-covered business, present a greater food safety risk than those of larger firms. Comments we received on the proposed rule have not presented any information tying risk of adulteration to firm size to persuade us that we should apply the requirements of this rule to the businesses we proposed to exclude. Operators of small box trucks would be covered unless they meet the definition of a non-covered business.

To further expand upon our thinking, we note that the preventive controls rules exempted "qualified facilities" as defined by the FSMA, from the requirement for hazard analysis and risk-based preventive controls and instead established very limited requirements (essentially statutorily mandated attestations by the firm to FDA) specific to this category of facilities, *e.g.*, "very small businesses," as defined in these rules. While the 2005 SFTA does not address "qualified" facilities and does not require us to include provisions in this rule for very small businesses, we determined in considering the costs and benefits of this rule, that a category of businesses, *i.e.*, "non-covered" businesses, should remain subject to the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations, but not be subject to the requirements of this rule. We point out that many non-covered businesses that are shippers, loaders and receivers, would be subject to the cGMP provisions in § 117.93 of the preventive controls rule that address transportation practices. We also point out that our proposed approach would not absolve a non-covered business from the responsibility to conduct its transportation operations in compliance with the adulteration provisions of the FD&C Act, upon which this rule is based.

Therefore we are retaining the exclusion for non-covered businesses from the requirements of this rule. However, to further promote the application of sanitary transportation practices throughout the industry, we will also consider establishing guidance for transportation activities carried out by non-covered businesses.

(Comment 63) Some comments are concerned about possible unintended consequences potentially associated with size-based exclusions, including confusion that could result when a covered firm attempts to do business with a non-covered firm, or the exit of small firms from the food transportation industry because shippers may discontinue doing business with carriers that are not subject to the rule. One comment opposed to the proposed provision expresses the view that small shippers, loaders, carriers, and receivers excluded from the rule based on size still could be penalized if the food they are transporting becomes adulterated because any party that introduces or receives an adulterated food product in interstate commerce may be held legally responsible.

(Response 63) Firms engaged in food transportation, including those exempt from this rule, must comply with all of the generally applicable requirements of the FD&C Act, including those that prohibit the holding of food under insanitary conditions whereby the food may become contaminated with filth or be rendered injurious to health. While differing requirements have the potential to affect business relationships among firms and their interactions with regulatory agencies, we believe that agencies and the marketplace can adapt appropriately, and that firms will not be unduly inconvenienced by them. Furthermore, if firms that are not covered by this rule because of their size voluntarily chose to meet the rule's requirements, for example, for competitive business purposes, there are resources, such as FDA and industry issued guidance on sanitary food transportation and training in sanitary food transportation practices, available to them.

(Comment 64) One comment states that the proposed exclusion may have the unintended consequence of motivating food transportation firms to create subsidiary companies for the purpose of dispersing their annual sales so that each newly created, related company would have less than $500,000 in annual sales, and therefore qualify for the exclusion.

(Response 64) In the proposed rule (79 FR 7006 at 7014) and in the responses to the previous comments, we articulated our reasons for excluding a "non-covered business" from the requirements of this rule. We cannot discount the possibility that some firms might form separate businesses to bring their disaggregated annual sales below the threshold for a non-covered business, but this is not likely to be a common occurrence and such separation may not be advantageous for business reasons. Therefore, we do not believe that the possibility poses a reasonable basis upon which to modify this provision of the rule.

(Comment 65) Among comments that we received in support of the proposed exclusion for non-covered businesses, some support keeping the provision at its proposed threshold of $500,000 in total annual sales. Another comment supports lowering the annual revenues threshold to $10,000, while a few support increasing it to $1,000,000. One comment supports the exclusion, but suggests defining a non-covered business exclusively as one that employs fewer than 500 people, regardless of annual revenues. According to this comment, annual revenues can vary from firm to firm, depending on the food products involved, for example, the differences between the prices of commodity items and premium or gourmet items. This comment proposes using a threshold of $1,000,000, consistent with the highest threshold in the proposed preventive controls for human food rule, in the event we decline to define a non-covered business in terms of the number of people employed. Another comment supports an increase in the threshold without explicitly suggesting a new one. Finally, one comment supporting the exclusion provision asks us to explicitly state that it would extend to foreign firms engaged in food transportation activities.

(Response 65) We explain our reason for retaining the exclusion of non-covered businesses from the requirements of this rule in our response to Comment 62. We are retaining the threshold for a non-covered business as a total annual revenues based threshold at the $500,000 level as proposed; however, we are allowing for adjustment for inflation and for basing the calculated value on average annual revenues, calculated on a rolling basis, during the 3 preceding years. We estimate that removing firms below this threshold from coverage by the rule would result in about 5 percent of food shipments not being covered by this rule

To define a non-covered business as one not exceeding $10,000 in total annual sales, as one comment suggests, would not be consistent with our stated purpose of extending comparable treatment to firms subject to this rule and similarly situated firms subject to the FSMA preventive controls rules. A $10,000 total annual sales limit corresponds to a business of much smaller size than one that could be a "qualified facility" as defined in the preventive controls rules and such a threshold would likely result in 100 percent of food shipments being covered by the rule.

We considered changing the total annual sales limit for a non-covered business to $1,000,000, which would be consistent with the definition of very small business in the Human Food Preventive Controls rule (the Animal Food Preventive Controls rule defined very small business as less than $2,500,000), but chose not to do so because it would result in about 10 percent of food shipments not being covered by this rule. While selecting a value of $1,000,000 for this rule would be more consistent with the Preventive Controls rules, which we believe to be a desirable endpoint, the percentage of food shipment not covered by this rule at that threshold would be vastly different than the less than 0.6 percent of food not covered by the Preventive Controls rules. We weighed the cost to this category of small businesses against the risk of adulteration, and determined that excluding 5 percent of shipments from coverage by this rule was more appropriate, because it would expose less food to any potential risk arising from non-coverage by this rule.

We decline to establish the threshold for a non-covered business in terms of fewer than 500 people employed, because that threshold is the basis of the definition of a "small business" under this rule, which is a covered business category.

(Comment 66) One comment asks us to add an additional exclusion for food establishments that sell to qualified end users, as defined by the FSMA preventive controls rules, as a separate category within the definition of "non-covered business," or as a separate exclusion, rather than requiring this category of businesses to undergo the waiver process provided for in this rule. The comment states that such an exclusion would follow FSMA's mandate for the preventive controls rules and produce safety rule to be flexible, and scale- and supply-chain appropriate. The comment states that this mandate includes content requirements for the preventive controls rules and the produce safety rule to provide sufficient flexibility to be practicable for all sizes and types of businesses and facilities, and to provide modified requirements for small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains.

(Response 66) The Preventive Controls rules for human and animal food provide for modified requirements for qualified facilities. Qualified facilities are defined in those rules to mean a facility that is a very small business (*i.e.*, averaging less than $1,000,000 of annual sales of human or animal food), or a facility to which both of the following apply: (1) The average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (2) the average annual monetary value of all food sold was less than $500,000. A qualified end-user is defined to mean the consumer of the food or a restaurant or retail food establishment that: (1) Is located: (i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or (ii) not more than 275 miles from such facility; and (2) is purchasing the food for sale directly to consumers at such restaurant or retail food establishment. In sum, facilities that sell less than $1,000,000 of food are subject only to the modified requirements of the Preventive Controls rules, whether or not those sales are to qualified end users.

As explained in our response to previous comments, we have attempted to make consistent, to the extent possible, the size-based "exemption" from this and the Preventive Controls rules. Because we did not "exempt" from the preventive controls rules (*i.e.*, subject to only the modified requirements) all firms that make sales to qualified end users, as suggested by the commenter, we are similarly declining to do so here. As a practical matter, however, the $500,000 exemption provided for in this rule applies whether or not the sales are to qualified facilities, as does the $1,000,000 threshold in the Preventive Controls rules. We explain in the preceding comment response why we did not select a $1,000,000 threshold in this rule.

Nevertheless, we stated in the proposed rule (79 FR 7006 at 7029–7030) that we had tentatively determined that it would be appropriate to waive the applicable requirements of this rule, if finalized as proposed, with respect to retail food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment. As we stated in section III.E., we intend to publish a waiver in the **Federal Register** addressing this class of persons prior to the compliance date of this final rule.

13. Person

In the proposed rule we defined "person" to mean individuals, partnerships, corporations, and associations. We have deleted this definition from this final rule, however, because § 1.904 of the rule clearly states that the definitions and interpretations of terms in section 201 of the FD&C Act are applicable to such terms when used in this rule. We did not receive any comments on our definition of the term "person."

14. Pest

We proposed to define the term "pest" to mean any objectionable animals or insects including birds, rodents, flies, and larvae. We are finalizing this definition as proposed.

(Comment 67) One comment states that, while the utmost care is taken to ensure that natural pests of tree fruit are eliminated during the packing process, the presence of naturally occurring plant pests in tree fruit is not an indication of contamination and, if found, should not be cause for concluding that the tree fruit is adulterated.

(Response 67) There is no provision in this rule by which we would automatically regard the presence of naturally occurring plant pests in tree fruit as grounds for determining that the food is unsafe. We do not intend to establish a standard for the adulteration of tree fruit because of the presence of naturally occurring pests. As we discuss in response to Comment 89, we have revised the provisions of the proposed rule that incorporated the adulteration provisions of the FD&C Act in addressing transportation equipment and operations. As we explained, we did this to avoid misinterpretation of this rule and to clarify that this rule only requires that transportation operations, including the use of transportation vehicles and equipment, must be conducted under conditions and controls necessary to prevent the food from becoming unsafe, *i.e.*, adulterated within the meaning of sections 402(a)(1), (2) and (4) of the FD&C Act.

15. Receiver

We proposed to define "receiver" to mean any person who receives food after transportation, whether or not that person represents the final point of receipt of the food. We further clarified in the proposed definition that the receiver may also be a carrier or a shipper and that a receiver does not include an individual consumer or a person who holds food on behalf of an individual consumer and who is not also a party to the transaction and not in the business of distributing food. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of "carrier," "shipper" and "receiver." We have also removed the specificity about the consumer or someone acting on his or her behalf because it was inappropriate for a definition, but we affirm that these entities are not subject to this definition. We did not receive any comments on our proposed definition of "receiver."

16. Shelf Stable

We proposed to define the term "shelf stable" to mean a food that can be stored under ambient temperature and humidity conditions and, if the package integrity is maintained, will not spoil or become unsafe throughout its storage life. Examples of shelf stable food include canned juices, vegetables, and meat, bottled water, and dry food items such as rice, pasta, flour, sugar, and spices. We are removing this definition from the final rule because the proposed exclusion (in the definition of "transportation operations") of "shelf stable food that is completely enclosed by a container" has been changed to apply to "food that is completely enclosed by a container except a food that requires temperature control." We made this revision in the definition of "transportation operations" because, as we have previously explained, we have narrowed the focus of this rule to adulteration linked to food safety.

While some non-shelf-stable foods that are completely enclosed by a container and do not require temperature control for safety, *e.g.*, pasteurized orange juice, may spoil and become unfit for consumption if temperature abused, such a food will not become unsafe. The adulteration of food in such a circumstance, due to spoilage, would have been subject to this rule as proposed. This is no longer the case, nonetheless, FDA has authority under existing adulteration provisions in section 402 of the FD&C Act to address such a circumstance. We are addressing comments that spoke to the proposed exclusion of shelf stable food from the transportation operations definition to better inform readers about the scope of foods that would fall within the broader exclusion in revised definition.

(Comment 68) One comment states that we should clarify the definition of "shelf stable food" so that it clearly applies to all shelf stable foods, including food ingredients such as flavoring substances and compounded flavors. The comment states that our proposed definition for "shelf stable foods" may be construed too narrowly because the examples we provided in the proposed language imply that the "shelf stable food" definition applies only to finished food products like canned juice, canned vegetables, or bottled water. The commenter voiced the view that it is unclear from the proposed rule whether we intend for that list to be exhaustive or exclusive. The comment asks us to ensure that the definition clearly applies to all foods, including food ingredients that meet the "shelf stable food" definition. Another comment recommends that we include examples of animal food, such as packaged animal food, in the definition of shelf stable food.

(Response 68) We agree with these comments and affirm that food "completely enclosed by a container," as expressed in the definition of "transportation operations" encompasses food ingredients as well as finished food products for humans and animals. We are not including examples of such foods because this category of food is extremely broad, making any such list limited relative to the whole, and we believe that the revised definition describes the types of foods encompassed by this exclusion in an understandable manner.

(Comment 69) Some comments state that shippers and carriers need more clarity on which food shipments are shelf stable. One comment states that the proposed definition provides a broad description of what constitutes shelf stable food but does not contemplate the diverse characteristics of food items, such as shelf-lives, packaging, and handling requirements that shippers and carriers will need to consider when determining whether food is shelf stable. The comment, for example, asks: How long the shelf-life of an item must be before it is considered shelf stable; whether packaging susceptible to humidity or humidity abuse would be considered to be fully enclosed, *i.e.*, whether we would question if packaging susceptible to humidity or humidity abuse is capable of maintaining package integrity; and whether we would consider food items subject to spoilage when frozen and thawed at room temperature to be shelf stable? Another comment asks us to affirm that boxes with flaps that are sealed by tape qualify as acceptable packaging under this definition. This comment also asks us to affirm that this definition does not only apply to food products bound for retail outlets, but would also apply to food being shipped from a supplier to a re-packer. Another comment states that we should require shippers or loaders to give carriers unambiguous notice when they are given shipments of food that are not shelf stable.

(Response 69) The shipper of the food, who often is also its manufacturer, would be the person who would be expected to know whether a food falls within the scope of the exclusion from the definition of "transportation operations" applicable to food completely enclosed by a container and that does not require temperature control for safety. We would expect that the shipper would take the steps required under this rule with respect to the transportation of any food that falls within the scope of this definition. This rule does not require the shipper to inform the carrier that a shipment of food is not subject to this rule because it is excluded from the scope of this definition.

In addressing the other questions raised by these comments we can state: (1) The requirements applicable to any food subject to this rule apply during transportation to all receivers that are subject to this rule, not just food bound for retail outlets; (2) In general, we would consider boxes with flaps sealed by tape to be a container that completely encloses the food; (3) The transportation of frozen food is not subject to this rule. As we stated in the proposed rule for preventive controls for human food (78 FR 3646 at 3774), the temperature and time required for a frozen food to become unsafe if not maintained in the frozen state would result in significant quality issues for the food before posing any safety risk, and as we discuss elsewhere in this final rule, we have narrowed the focus of this rule to adulteration linked to food safety; (4) There are packages which physically separate food from its surrounding environment that, nonetheless, allow for oxygen and atmospheric moisture exchange (*e.g.*, paper, cardboard) under reasonably anticipated storage conditions during transportation, and for which we would regard the food to be completely enclosed by a container because the container would protect the food from any contamination that could directly enter the food from the environment; and (5) If a shelf stable food's container is subjected to abusive storage conditions during transportation which may compromise its package integrity and allow moisture to enter the food, the food product is not within the scope of the "transportation operations" definition, however, we would make a case-by-case determination as to whether the food complies with the requirements of FD&C Act, particularly, section 402(a)(4) which states that "a food shall be deemed to be adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health."

17. Shipper

We proposed to define the term "shipper" to mean a person who initiates a shipment of food by motor vehicle or rail vehicle. We further clarified in the proposed definition that the shipper would be responsible for all functions assigned to a shipper in this subpart, even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper, and that a shipper may also be a carrier or a receiver if the shipper also performs those functions as defined in this subpart. We are finalizing a simplified definition of "shipper" to mean a person who arranges for the transportation of a food by a carrier or multiple carriers sequentially. A "shipper" could be a manufacturer or a freight broker. In the final rule, as explained in the discussion of § 1.908(a)(1), we have added a general provision about the multiple roles that can be played by a single entity to replace the separate provisions we had included in the proposed definitions of "carrier," "shipper" and "receiver". We explain our consideration of comments and our reasons for revising the final definition in the responses to Comment 70.

(Comment 70) Several comments oppose defining a shipper as the person who "initiates" transportation. One comment states that the term is unnecessarily broad and would create confusion about who is subject to the shipper requirements. Another comment states that the meaning of the proposed definition is unclear because shipments of food can be initiated by many different types of persons during the transportation process, such as manufacturers, distributors, brokers (parties who arrange for the transportation of food held by other parties), and retailers. Another comment states that the shipper definition should describe the person who performs an activity directly related to the transportation process.

Several comments suggest changes to the proposed "shipper" definition. Some stated that the shipper should be the person who physically loads or orders the loading of a motor vehicle trailer or railcar. Some comments state that the shipper should be the manufacturer of the food because that person is most knowledgeable about all relevant factors concerning sanitary transportation of the food. One comment states that the shipper should be the person who decides to ship a food product and sets the transportation process in motion.

Other comments state that the shipper should be the person who owns the food at the time of shipment. One of these comments notes that product owners can best meet the responsibilities assigned to a shipper under the proposed rule even when another party arranges for the transportation of the shipment. The comment states that it is common industry practice for owners of the product to provide third-party logistics providers with instructions for the conditions required for shipments. Several comments advocating these revisions state that their suggested changes would clarify which entities in the transportation chain must meet this rule's requirements for shippers.

Other comments state that the shipper definition should not place shipper responsibilities on persons such as brokers because they lack knowledge about food safety and sanitary food transportation practices. One comment stated that third-party logistics providers, such as distribution centers, should not be subject to the shipper definition. The comment states that, although third-party logistics providers arrange for the transportation of food, they lack knowledge about food safety and rely on product owners to provide that information in establishing sanitary transportation conditions.

One comment stated that brokers are nowhere near the location where a shipment of food is being loaded into a motor vehicle trailer or railcar and, therefore, it is impossible for them to carry out duties assigned to a shipper, such as visually inspecting a vehicle prior to loading. A related comment asserts that facilities that hold the food for which shipment is arranged by an offsite shipper should be responsible for proper storage, handling, and loading or unloading of the food in accordance with FDA and customer requirements. Another comment addressed concerns that under the proposed shipper definition, shipper responsibilities would fall upon receivers who purchase food under a FOB contract in which title to the food passes at the seller's location, even though the receiver would not be present at the time of loading, and therefore could not meet this rule's shipper requirements. The comment states that the entity that physically loads the goods, instead of the receiver, is in the best position to meet a shipper's obligations, such as maintaining written procedures and records, and inspecting vehicles and transportation equipment prior to loading.

(Response 70) We agree that our proposed definition for a shipper, *i.e.*, the person who "initiates a shipment of food" is not sufficiently clear to identify the person who would be subject to this definition because the term "initiates" is not sufficiently precise. In considering how to revise this definition, we note that under the proposed rule, the shipper would be responsible for functions involving communication with the carrier that take place before transportation occurs (proposed § 1.908(b)(1) and (3)), and with functions involving the inspection of vehicles and transportation equipment that take place prior to loading (proposed § 1.908(b)(2) and (4)).

We first considered which person would be best suited to perform those functions, which involve specifying to the carrier all necessary sanitary requirements for the carrier's vehicle and transportation equipment to ensure that the vehicle is in appropriate sanitary condition, and specifying temperature control parameters to the carrier if the food requires temperature control during transportation. Inasmuch as these functions involve communicating important information to the carrier about operating conditions during transportation, we have determined that the appropriate person to perform these functions is the person who makes the transportation arrangements with the carrier because this person communicates directly with the carrier and can directly provide the carrier with the information required by this rule. While the owner or the manufacturer of the food, or the person who loads the food onto a vehicle, may possess this information, we do not regard these persons as best suited to bear responsibility for providing information to the carrier if neither of these persons actually makes the transportation arrangements with the carrier.

We also considered whether a shipper would need to be knowledgeable about food safety and sanitary transportation practices to perform functions that involve communication with a carrier before transportation occurs. While we agree that persons such as brokers, who arrange for transportation of food held by other parties, likely do not possess the degree of knowledge about food safety that a food manufacturer would, we also agree that current industry practices demonstrate that these persons, *e.g.*, brokers and other third-party logistics providers, obtain the vehicle preparation and sanitary transportation information, as needed, for example, from manufacturers, to provide to the carriers. Therefore, we do not regard brokers and other third-party logistics providers as inappropriate persons to perform the functions assigned to a shipper that take place before transportation occurs.

We have determined, therefore, that the person who arranges for the transportation of food by a carrier is best suited to perform the functions of a shipper that take place before transportation occurs and that the person can be someone who only arranges for the transportation of food, for example, a broker, as long as they have, or obtain, the necessary food safety information. We have incorporated these provisions into the revised definition of the term "shipper" in § 1.904.

We also considered the second function assigned to the shipper in our proposed definition, *i.e.,* those involving the inspection of vehicles and transportation equipment and confirming that the shipper's specifications have been met, *e.g.,* for cleaning and pre-cooling, which take place before food is loaded onto a conveyance. We agree with comments that state that a shipper who is not on site at the time of loading cannot readily perform these functions, and we do not believe that it would be practical to require an offsite shipper to arrange for a representative of the shipper to be present to perform these inspections. We therefore agree with the comment that states that these functions can be readily performed by the person who loads vehicles or transportation equipment if that person is not the shipper, provided that this person also receives the specifications for vehicle preparation that the shipper provides to the carrier under § 1.908(b)(1) and (2), because that person is on site and would typically be associated with the facility in which the food is held prior to loading. Further, the person likely would be knowledgeable with respect to basic sanitation practices applicable to loading food into vehicles and equipment because of his responsibilities in operating the facility. We also note that facilities that are subject to our cGMP requirements already have similar responsibilities under 21 CFR 117.93. This provision requires that storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

Therefore, we have determined that the shipper should not be responsible for the functions that person would have been assigned under § 1.908(b)(2) and (4) of the proposed rule involving inspection of vehicles and transportation equipment that take place prior to loading. We are defining an additional term, the "loader" as described previously in this section to designate the person who will be responsible for those functions under this rule under § 1.908(c), which has been redesignated in this final rule as "Requirements applicable to loaders engaged in transportation operations."

18. Small Business

We proposed to define the term "small business" to mean a business subject to § 1.900(a) that employs fewer than 500 persons, except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to § 1.900(a) that has less than $25,500,000 in annual receipts. In the final rule, we have revised the threshold for motor vehicle carriers to $27,500,000, consistent with the recent change made by the Small Business Administration in the size based standard for trucking firms in 13 CFR part 122.201. We have revised this final rule to base the calculation for "small business" on "full-time equivalent employees." We used the same approach to calculate full-time equivalent employees for the purpose of this rule as we used to calculate full-time equivalent employees in the preventive controls rules (*e.g.,* see response to comment 140 in the preventive controls for human food final rule (80 FR 55908 at 55962), and also the discussion of the definition of a full-time equivalent employee in that final rule (80 FR 55908 at 55962)). In conjunction with this revision and as previously described, we have established a definition for "full-time equivalent employee" as a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies as a small business for the purpose of establishing its compliance date. Therefore, we are modifying the definition of "small business" to use the term "500 full-time equivalent employees" rather than "500 persons."

(Comment 71) One comment states that the proposed definition of a small business is overly broad and would unduly delay the timeframe for compliance with this rule for the majority of the carriers.

(Response 71) We do not agree that our proposed definition is overly broad. As we explained in the proposed rule (79 FR 7006 at 7014), our proposed definition for a small business was based upon the applicable size-based standards issued by the U.S. Small Business Administration (SBA) under 13 CFR part 121. We believe that allowing businesses that are formally classified "small" by the SBA additional time to come into compliance with the requirements of this rule is appropriate. We also believe that small businesses that are able to come into compliance before their compliance date would do so and use that fact for promotional purposes with prospective customer's, *e.g.,* shippers, rather than delay compliance with this rule.

(Comment 72) A comment stated that we should exempt Class II and Class III railroads (these classifications generally relate to short line and regional railroads respectively) with fewer than 400,000 labor hours from the requirements of this rule. The comment states that the 400,000 labor hours standard has been used by DOT from time to time as the standard for exempting small railroad carriers from regulatory requirements. The comment states that railroads are extremely capital intensive as they pay for their right of way and, typically, small business railroads invest much of their revenue into ties and track structure, equipment maintenance and inspections. The comment further states that shifting the responsibility for the sanitation of railcars carrying food products to the small railroad will be burdensome because these entities currently do not clean or sanitize cars or maintain facilities for such operations. Further, the comment states that it is difficult for railroads to know the storage condition of railcars, and that they cannot be reasonably held accountable for the storage conditions of cars in many circumstances of use.

(Response 72) As discussed in our response to Comment 53, we have revised the definition of the term "carrier" in this final rule, in part, because our proposed definition would have established requirements that railroad operators, typically, cannot meet. We stated that under the revised definition of the term "carrier" in this final rule, a railroad operator only bears responsibilities under this rule when it has agreed to do so in a written contract with the shipper. We believe that this revision addresses the concerns of this comment.

19. TCS Food

We proposed to define the term "time/temperature control for safety (TCS) food" to mean a food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. As we explained in our response to Comment 111, we have not retained this definition in the final rule. We, therefore, do not need to address comments that we received that suggest revisions or clarifications to the proposed definition.

20. Transportation

We proposed to define "transportation" to mean any movement of food in commerce by motor vehicle or rail vehicle. We did not receive any comment on our proposed definition and are finalizing it as proposed.

21. Transportation Equipment

We proposed to define the term "transportation equipment" to mean equipment used in food transportation operations, other than vehicles, for example, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, and loading and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor. We are finalizing this definition as proposed with the exception of the removal of the phrase "other than vehicles," which we are removing for clarity and the internal consistency of the definition.

(Comment 73) One comment asks us to revise the proposed definition of "transportation equipment" to clarify that it encompasses only such equipment exclusively associated with a transportation conveyance. The comment states that the proposed definition is overly broad, and could be interpreted to include structures and equipment normally associated with storage, load-out, and receiving procedures (such as loading bins, spouting and other equipment located within a shipper's or receiver's facility), and not strictly to equipment that directly facilitates transportation activities. The comment suggests that we use the following revised definition: "Transportation equipment means equipment used in food transportation operations, other than vehicles, *e.g.*, bulk and non-bulk containers, totes and pallets loaded onto transportation conveyances, and pumps, fittings, hoses, gaskets, loading systems and unloading systems that are integral and affixed to transportation conveyances."

(Response 73) We decline this request. The definition of "transportation equipment" already specifies that such equipment is used in transportation operations. While some types of equipment used in food transportation, such as hopper bins, may also be constructed as part of a facility, as we state in our response to Comment 52, we would not consider a hopper bin, that is constructed as part of a facility and that is used for storage of materials (but not the movement of food), to be transportation equipment. Therefore, it would not be subject to this rule.

22. Transportation Operations

We proposed to define the term "transportation operations" to mean all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspecting, maintaining, loading and unloading, and operating vehicles and transportation equipment. We further proposed that transportation operations do not include any activities associated with the transportation of shelf stable food that is completely enclosed by a container, compressed food gases, or live food animals and that all transportation activities involving raw agricultural commodities (RACs) that are performed by a farm are also excluded from the definition of the term "transportation operations." We are finalizing the definition of "transportation operations" as proposed with some additions. As we discuss in section IV.C., concerning our proposed definition of "shelf stable," which we have not retained in the final rule, we have amended the definition of "transportation operations" to specify that this term does not include activities associated with transport of a food completely enclosed by a container except a food that requires temperature control for safety. We have also added that transportation operations do not include activities associated with transport of food contact substances as defined in section 409(h)(6) of the FD&C Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. Finally, we have revised the exclusion for transportation activities performed by a farm to all transportation activities performed by a farm, not just those related to the transport of RACs. We explain our consideration of comments and our reasons for the revisions in our responses to the next 12 comments.

(Comment 74) A few comments ask us to consider excluding, or granting a waiver for, the transportation of food additives and substances that are generally recognized as safe (GRAS), and their precursors, from the proposed requirements of this rule. One comment states that these substances always undergo further inspection, testing, and processing steps, which minimizes the possibility that they could render the food ingredient, or the food that the ingredient is eventually incorporated into, adulterated. One comment states that exemption or waiving is appropriate because the production and supply chain for these substances includes controls to prevent contamination during production, packaging and transport, and is often certified by third parties. One comment urges us to apply this rule's provisions for prior cargo disclosures, protections from allergen cross-contact, and recordkeeping to these substances. The comment expresses the view however that a shipper should be exempted from even these requirements if it can demonstrate that its food additives and GRAS substances have not been transported in containers that have come into contact with any of the seven major food allergens, either because these products are not comingled with other foods or because the carrier does not transport any other food items.

(Response 74) We decline these requests. We acknowledge that food additives, GRAS substances, and their precursors may undergo further inspection, testing, and processing that minimizes the possibility that they could render food adulterated, or that they may be subject to controls and third-party certification that address protection of the substance during transportation. However, this is a broad group of substances with diverse packaging and transportation practices (*e.g.*, bulk shipments), and it is likely that there are substances for which the controls included in this final rule are necessary to ensure sanitary transportation, depending upon the nature of the substance, the method used to transport it, and its intended use. Therefore, exempting or waiving food additives and GRAS substances and their precursors from the requirements of this rule would not be appropriate. However, we have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transportation of these substances to use sanitary transportation practices that are appropriate for their circumstances.

(Comment 75) One comment asks us to consider excluding shippers and carriers who transport byproducts from a processing facility, *e.g.*, spent grain from alcoholic beverage production facilities, from this rule. The comment states that many industries have developed sustainable and cost-effective ways to use these byproducts as animal feed. The commenter believes that the new recordkeeping and inspection requirements proposed in this rule would hinder a beneficial practice that has worked successfully for many years.

(Response 75) We have partially accommodated this request in this final rule by excluding from the definition of transportation operations, "human food byproducts transported for use as animal food without further processing." The intent of this new language is to exclude from the definition human food byproducts that are not further processed into a manufactured animal feed. Most commonly, we expect that these byproducts move directly from the human food manufacturer to the farm, where they are fed directly to livestock, often by spreading on the ground. We do not intend to exclude from the definition of transportation operations human food byproducts that are transported to a business to be used as an ingredient in a manufactured animal food, or to be further processed in some way (*e.g.*, rendered) in the production of animal feed. We believe the scale of the public health risk posed by the former activity to be minimal, with the byproducts being transported to only one or several farms, while the scale of the public health risk posed by the latter would be substantially greater, with the byproducts being manufactured into large quantities of animal feed, possibly with a wide distribution. Our concern here is primarily with the potential for chemical contamination, as we are aware that many of the byproducts will be heat treated (*e.g.*, rendered) in a way that will minimize the risk of microbiological contamination.

With respect to transportation of human food byproducts for further processing into animal feed, we decline the request to remove such operations from the definition of transportation operations because we have determined that this final rule's recordkeeping and inspection requirements as applied to the transportation of such products are not burdensome and are appropriate for these types of transportation operations. The requirements we are establishing in this rule require that transportation operations be conducted so as to prevent food from becoming adulterated during transportation. We do not envision, for example, that carriers who transport spent grain materials to animal feed manufacturing facilities would have to clean or inspect their vehicles any more frequently under this final rule than what is already typically being done to facilitate safe transportation. However, if carriers haul intervening loads of fertilizer, for example, they would need to clean their vehicles before transporting spent grain intended for use as animal feed. In addition, as we explained in our response to Comment 149 and Comment 160, in § 1.908(e)(4) and (e)(5) of this final rule, we have revised the proposed previous load and cleaning reporting requirements for bulk carriers in a manner that will reduce, and in some cases eliminate, recordkeeping requirements for these carriers.

(Comment 76) Several comments support our proposed provision that would exclude the transport of live animals from the definition of "transportation operations." One comment disagrees with our tentative conclusion that sanitary transportation practices are not necessary to prevent live food animals from becoming adulterated during transportation and our proposal, therefore, to exclude their transport from the scope of this rule. This comment suggests that transportation during hot and cold weather, as well as long-distance transport, causes stress in the animals, resulting in increased shedding of pathogenic microorganisms in the manure of the animals being transported. The commenter asserts that these pathogenic microbes may be spread from one animal to another via physical contact in transportation vehicles, possibly resulting in a higher percentage of animals arriving at slaughter facilities with high levels of pathogenic microbes on their hides or feathers. The comment asserts that the more animals that arrive at slaughter with pathogens on their hides or feathers, the more likely that the mitigations applied by the slaughter facilities will be ineffective. The commenter further asserts that FSIS inspection at slaughter facilities is inadequate to mitigate this increase in risk and, therefore, asks us to require the cleaning of transportation vehicles with disinfectants between animal loads to mitigate the risk.

(Response 76) We disagree with this comment. We recognize that the stress of transportation may increase the shedding of pathogenic bacteria in the manure of animals during transport, but we are not aware of scientific information that establishes that this leads directly to an increased level of pathogenic bacteria in food products originating from animals coming from FSIS-inspected slaughter facilities that could be controlled by establishing requirements through this rulemaking. The slaughter facilities handling the processing of these animals, as well as the regulatory agencies responsible for oversight of the facilities, such as the FSIS, are aware of these issues and the procedures they use to process these animals have been developed with this risk in mind. Slaughter operations at facilities subject to FSIS jurisdiction, for example, are already subject to requirements intended to minimize the risk of adulteration posed by the presence of contaminants on the external surfaces of live food animals.

(Comment 77) One comment asks us to apply this rule's waiver provisions to determine whether to waive requirements for the transport of live food animals. The comment further asserts that we should use the waiver procedure, in part, to provide for an additional opportunity for public comment with respect to the risks that may be associated with the transportation of live food producing animals.

(Response 77) We disagree. Section 416(d)(1)(A–B) of the FD&C Act provides us with the authority to waive any requirement of this rule with respect to any class of persons, vehicles, food, or nonfood products, if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health, and will not be contrary to the public interest (21 U.S.C. 350e(d)(1)(A–B)). As we discussed in the proposed rule (79 FR 7006 at 7015), we are not aware of food safety concerns related to the transportation of live food animals intended for slaughter that could be addressed through this rule's sanitary transportation requirements. Furthermore, we also address specific concerns the commenter raised about this issue in our response to Comment 76, and explain why we have concluded that establishing requirements through this rulemaking to address those concerns is not necessary. The prerequisite condition for considering whether we should waive the requirements of this rule for the transportation of live food animals therefore does not exist, *i.e.*, we are not aware of any concerns that would necessitate establishing sanitary transportation requirements applicable to live food animal transportation and, therefore, there are no requirements to waive. We, therefore, have recognized in our definition of "transportation operations" that the transportation of live food animals does not meet the criteria for inclusion in this definition.

(Comment 78) One comment on our proposed definition of "transportation operations" notes that the exclusion of live food animals from the definition possibly conflicts with our own guidance under the National Shellfish Sanitation Program (Ref. 26). It stated that some states, operating under FDA guidance, require temperature control during the transport of raw molluscan shellfish between the harvest area and the first receiver (also known as the "dealer"). Participants made similar comments during the public meetings that we held on this proposed rule.

(Response 78) We agree that temperature control is necessary to ensure the sanitary transportation of molluscan shellfish (*e.g.*, oysters, clams, mussels) when transported live. As such, and to maintain consistency with guidance we have issued, we have revised the definition of "transportation operations" to state that molluscan shellfish are not included in the provision that otherwise excludes the transportation of live food animals from this definition.

(Comment 79) Many comments support the exclusion of transportation activities for RACs performed by farms and voice the view that the exemption should be retained in our final rule. Several comments advocate for limiting the exclusion only to RACs that will undergo further processing and a kill step before they are consumed. The comments argue that RACs covered by the produce safety rule will not be processed further before being consumed and therefore are particularly at-risk for becoming contaminated during transportation. Some comments oppose this exclusion provision. Some of these express the view that requirements for the same activity should not differ based on who performs the activity and argue that farm trucks transporting RACs should be covered under this rule. Another comment asks us to include a separate section in this rule that would apply to transportation activities for RACs performed by farms, and states that RACs transported by farms at a minimum should be subject to the rule's modification or revocation procedures applicable to waivers. One comment asks us to engage with industry and other key stakeholders, including trade associations, to establish a maximum distance that a farm exempt from this rule should be able to transport RACs.

(Response 79) We are not aware of food safety concerns related to the transportation of RACs by farms that could be addressed through the sanitary transportation practices set forth in this rule, as we stated in the proposed rule (79 FR 7006 at 7016). We also stated in the proposed rule that we are not aware of instances in which insanitary conditions or practices, for example, improper temperature control, improper equipment construction, or inadequate equipment cleaning involving the transportation of RACs by farms have contributed to foodborne illnesses. We further stated that we recognize the diversity of farms and their transportation operations, including the size of the operation, the nature of the crop(s) being transported (*e.g.,* large trailer loads of dry grain or livestock, small loads of fresh produce or shell eggs), the nature of existing transportation equipment (*e.g.,* large tractor-trailers, small farm trucks and wagons), and the destination of the shipment (*e.g.,* a local cooling facility, farmers market or restaurant, a more distant market), and the challenge that this diversity presents in developing a set of mandatory requirements that would be practical and broadly suitable for this sector. Therefore, we tentatively concluded that the sanitary transportation practices that would be required by this proposed rule are not necessary to prevent RACs from becoming adulterated during transportation by farms. We acknowledged that transportation from farm to market is often performed by independent carriers as arranged by shippers or receivers that are not farms. Similarly, farms may arrange for transportation (*i.e.,* serve as a shipper) by a common carrier. Transportation by independent carriers, as compared to farms, is likely to be over long distances and to involve the use of much larger vehicles and transportation equipment that is generally more consistent with equipment used outside the farm sector. Furthermore, long distance transportation operations may involve several stops for dropping and picking up additional loads. Communication and coordination between carriers, shippers and receivers is a critical element in properly carrying out such transport where different parties are handling various transportation responsibilities, as opposed to transport performed by a farm where the farm is responsible for all of the roles covered by this rule except the receiver. To advance best practices for the transport of produce, the industry has developed guidance that addresses among other things, recommended practices for independent carriers (Ref. 27). Building on industry experience we have concluded that the requirements of this regulation should not apply to such carriers with regard to the transportation of food by farms. We did not receive any comments to the proposed rule that would cause us to alter our determination to provide this exclusion or that convince us that modifications or qualifying conditions should be added to the proposed exclusion for transportation of food by farms.

Upon further consideration, we have also concluded that the exclusion from the transportation operations definition related to transportation activities performed by farms should not be limited to RACs. We are aware that farms ship and receive food items that are not RACs (*e.g.,* feed received to sustain their livestock, value added packaged food, such as jams, honey, baked goods) and that these food items are transported in the same manner as described earlier in this document for RACs. We have concluded that the diverse handling of these non-RAC food items by farms presents the same challenge for developing a set of mandatory requirements that would be broadly suitable for this sector, as described earlier in this document for RACs. For this reason, we are removing the limiting clause "for raw agricultural commodities" from the exclusion of transportation activities performed by farms from the definition of transportation operations. Consistent with the preamble to the proposed rule, the exclusion is intended to apply to the activities of farms, regardless of whether the farm is serving in the role of shipper, loader, carrier, or receiver.

Section 416(d)(1)(A) and (B) of the FD&C Act provides us with the authority to waive any requirement of this rule with respect to any class of persons, vehicles, food, or nonfood products, if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health, and will not be contrary to the public interest. As we discussed in the proposed rule with respect to the transportation of RACs (79 FR 7006 at 7016), and are affirming herein, and as we discussed previously in this response with respect to other types of food transported by farms, we are not aware of food safety concerns related to transportation activities performed by farms that could be addressed through the sanitary transportation practices set forth in this rule. Accordingly, the prerequisite condition for considering whether we should waive the requirements of this rule for transportation activities performed by farms does not exist, *i.e.,* we are not aware of any concerns that would necessitate establishing sanitary transportation requirements applicable to such transportation operations, and therefore there are no requirements for us to consider waiving.

(Comment 80) One comment asserts that if transportation activities for RACs performed by a farm are excluded from this rule, we should clarify that a carrier would not be held responsible for any contamination that may have occurred before the RACs were loaded into the carrier's vehicle.

(Response 80) Under this final rule, as revised, transportation activities for any food, including RACs, performed by farms, while not subject to the requirements of the rule, are still subject to the adulteration and other applicable provisions of the FD&C Act and our applicable implementing regulations. A farm that acts as a carrier, for example, that transports RACs and that is excluded from this rule, is still subject to section 402(a)(4) of the FD&C Act, which prohibits the holding of food under insanitary conditions whereby it may be rendered injurious to health or may become contaminated with filth.

(Comment 81) One comment asks us to clarify whether fruit transported to a processing facility falls under the proposed exclusion for the transportation of RACs performed by a farm.

(Response 81) Transportation activities for RACs, including fruit, to processing facilities are excluded from coverage under this rule, only if the activity is performed by a farm as defined in this rule. However, farms subject to the produce safety rule will be required to take steps to address the transportation of covered produce under that rule. Section 112.125 of the produce safety rule requires that equipment subject to that rule that is used to transport covered produce must be adequately clean before use in transporting covered produce and adequate for use in transporting covered produce.

(Comment 82) One comment asks us to clarify whether this rule applies to dairy farmers who transport bulk animal feed in their own vehicles from a facility to their own farm. A second comment asks us to clarify whether almond hulls and shells are eligible for the rule's RACs transported by farms exemption.

(Response 82) As we discuss in Comment 79, we have revised this final rule to provide that all transportation activities performed by a farm, and not solely those activities involving the transportation of RACs, are not subject to this rule.

(Comment 83) Some comments ask us to clarify whether this rule applies to non-farm carriers who transport RACs on farms or from farms to processing facilities where additional sanitation procedures or microbial kill steps occur, for example, when fruit RACs are processed at the receiving facility into canned fruit. Some comments argue that RACs that are moved on a farm or from a farm to a processing facility should not be subject to the requirements of this rule, regardless of who owns and operates the vehicles and transportation equipment.

(Response 83) Non-farm carriers, unless they are non-covered businesses, engaged in transportation operations, as defined by this rule for RACs, are subject to this rule regardless of whether the RACs are intended to be further processed. While the RACs in question may be further processed, there may be circumstances in which controls, for example, a specific vehicle cleaning procedure, are necessary to ensure that sanitary transportation practices are followed. We have added provisions to § 1.908(a)(3) of this rule to provide sufficient flexibility to allow persons engaged in the transport of food intended for further processing to use sanitary transportation practices that are appropriate for their circumstances. The movement of RACs on a farm that have not entered commerce is not subject to this rule because such on-farm movement is not considered to be transportation, as defined in this rule.

(Comment 84) One comment agrees that transportation of a shelf stable food that is completely enclosed by a container should be excluded from coverage under this rule, as we proposed. It states that, in addition, the exclusion should be extended to those same materials shipped in dedicated bulk containers, so long as the containers meet the criteria for sanitary food transportation.

(Response 84) We wish to make it clear that this comment addresses transportation equipment and not vehicles. We agree with this comment provided that the shelf stable food as packaged within the equipment, *i.e.,* the reusable dedicated bulk container, is completely enclosed by the container. As provided under the revised definition of "transportation operations," the described container, when used to transport any food that does not require temperature control for safety, meets the criteria for exclusion from the definition of "transportation operations."

(Comment 85) Several comments ask us to delete the word "solely" from the language in the definition of transportation operations excluding activities associated with the transportation of shelf stable foods from this definition. One comment states that the term "solely" is confusing and appears to suggest that shelf stable food should be shipped in separate loads apart from non-food items and other covered food items.

(Response 85) We agree that the word "solely," as used in the proposed definition of "transportation operations," may be confusing and we have concluded upon further consideration that it is not necessary. We, therefore, have removed the term "solely" from the definition of transportation operations.

23. Vehicle

We proposed to define the term "vehicle" to mean a land conveyance that is motorized, *i.e.,* a motor vehicle, or that moves on rails, *i.e.,* a railcar, which is used in transportation operations. We are finalizing this definition as proposed.

(Comment 86) One comment asserts that the definition of "vehicle" as any "land conveyance that is motorized" and the use of the term "motor vehicle" are excessively broad and could be misinterpreted to include a wide range of motorized vehicles, including automobiles. The comment also notes that there are instances in which railcars, trucks, and trailers can be used to store food products. This comment asks us to narrow this definition to read: "Vehicle means a truck or railcar, which is used in transportation operations and not to hold food."

(Response 86) We decline to make the suggested change. The definition of vehicle is intentionally broad and could include automobiles. We do agree that sometimes railcars, trucks, and trailers can be used to store food products, and we will incorporate that possibility into our implementation of this rule. A truck or trailer used for the permanent or semi-permanent storage of ingredients or finished food products is not within the scope of this rule and could be considered as part of a facility and regulated under another of our applicable regulations, *e.g.,* the FSMA human or animal preventive controls rules that apply to the facility. A truck, trailer, or railcar being used, or being prepared for use, to transport human or animal food or food ingredients, would be subject to this rule. In either case, the equipment would need to be used in a manner consistent with the appropriate set of regulations, and in such a way that the food is not rendered unsafe.

D. What requirements apply to vehicles and transportation equipment? (§ 1.906)

In table 7 we outline the revisions we have made to § 1.906 in finalizing this rulemaking. Following the table we respond to comments about these provisions and describe the changes we have made to the provisions in finalizing the rule.

TABLE 7—§ 1.906 WHAT REQUIREMENTS APPLY TO VEHICLES AND TRANSPORTATION EQUIPMENT?

Proposed section (§)	Description	Revision
1.906(a)	Specifies that vehicles and transportation equipment must be designed and of such material and workmanship to be suitable and adequately cleanable for their intended use to prevent food from becoming adulterated.	Removed the text that described the goal of the provision to be prevention of food from becoming "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source" from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with "to prevent the food . . . from becoming unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act."
1.906(b)	Specifies that vehicles and transportation equipment must be maintained in such sanitary condition for their intended use to prevent food from becoming adulterated.	Added "for their intended use" to the regulatory text for clarity. Removed the text that described the goal of the provision to be prevention of food from becoming "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source" from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with "to prevent the food . . . from becoming unsafe."
1.906(c)	Specifies that vehicles and transportation equipment used for food requiring temperature control for safety must be designed, maintained and equipped, as necessary, to provide adequate temperature control to prevent the food from becoming adulterated.	Removed the phrases "that can support the rapid growth of undesirable microorganisms in the absence of temperature control" and "maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms" from the regulatory text because our goal with this provision is prevention of adulteration linked to food safety. Revised regulatory text to specify that vehicles and transportation equipment used for food "requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe."
1.906(d)	Specifies that freezers and mechanically refrigerated cold storage compartments to be equipped with an indicating thermometer, temperature measuring device, or temperature recording device to show the temperature accurately with the compartment.	Removed this provision as unnecessarily prescriptive.
1.906(e)	Specifies that vehicles and transportation equipment must be stored in a manner that prevents harborage of pests or becoming contaminated in any other manner that could result in food becoming adulterated.	As a consequence of eliminating former 1.906(d), this provision is finalized as 1.906(d). Removed the text that described the goal of the provision to be prevention of food from becoming "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source" from the regulatory text because we have narrowed the focus of this rule to adulteration linked to food safety. In the final rule, we have replaced this text with "to prevent the food . . . from becoming unsafe."

1. Proposed § 1.906(a)

We proposed to require that vehicles and equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use, to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety as explained in responses to comments below, we have finalized this provision to require that vehicles and equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act during transportation operations.

(Comment 87) A comment from a non-profit organization that develops and updates equipment standards and processing practices asks us to include a provision in the final rule stating that vehicles and transportation equipment that have been fabricated in conformance with its standards and/or operated in accordance with its practices, and have been maintained in a sanitary manner, will be deemed to have met the minimum requirements of this rule.

(Response 87) We are not making this suggested revision. It is the responsibility of the persons subject to this rule to determine whether the vehicles and transportation equipment that they use or offer for use in food transportation operations meet the requirements of this rule.

(Comment 88) A few comments state that this regulation should not preclude the use of food transportation vehicles and equipment constructed of wood, and ask us to clarify under what conditions we would deem the use of vehicles and equipment constructed of wood to be acceptable.

(Response 88) Similar to statements we made in the produce safety rule (80 FR 74353) and final human food preventive controls regulation (80 FR 55908) about wooden bins, we are not precluding the use of transportation vehicles and equipment constructed of wood under this rule. However, where the intended use of the vehicle or equipment is such that food would be in direct contact with the wooden surface of transportation vehicles or equipment, we expect that such vehicles or equipment would be used only to the extent they are cleanable and unlikely to support conditions that may make the food unsafe (see Comment 95).

(Comment 89) Several comments address provisions of this rule for transportation equipment used in operations involving food materials destined for animal consumption. One comment asserts that the provisions in proposed 1.906(a), (b), and (e), do not seem to consider the transportation of materials that are already in a condition not suitable for consumption without further processing, such as viscera, offal, and other byproducts from the chicken slaughtering process. The comment notes that firms transport these materials to facilities where they will be further processed and treated to recondition the materials to make them suitable for animal consumption. Although the transportation conveyances used to transport these materials to processing facilities may, in fact, allow the growth of microorganisms during transport, the subsequent treatment process accounts for this and effectively renders the materials suitable for animal consumption. A similar comment states requiring transportation conveyances for animal food to be free of "filthy, putrid, or decomposed substances" should not apply to unprocessed raw materials destined for rendering. These materials include offal and trimmings from animal slaughter, dead animals, and spoiled or outdated meat from retail food establishments. They are transported by renderers in specialized equipment to prevent leakage and spills, but requirements related to refrigeration, microbial contamination, decomposition, and adulteration during transportation are not germane to these raw materials destined for further processing and hazard control. Another comment asks us to revise the rule to state explicitly that vehicles and transportation equipment must be designed, maintained, and stored in appropriate sanitary condition "for their intended use." According to this comment, doing so would clarify that different sanitary food transportation requirements can be applied to vehicles and transportation equipment, depending on the intended uses of the vehicles and equipment, while still making it clear that appropriate precautions must be followed in all circumstances. The commenter notes, for example, that although byproduct materials do not need to be transported under conditions that prevent them from becoming decomposed because they already are in this condition at the start of transportation, it would not be appropriate to transport these materials in a container that previously held a chemical contaminant that will not be eliminated through further processing if the container was not adequately cleaned before use.

(Response 89) We agree that in the proposed rule, we applied language from section 402 of the FD&C Act identifying circumstances under which food is adulterated in an overly broad manner so as to suggest, unintentionally, that any food in transport that exhibits any cited criteria of section 402 is adulterated, regardless of the nature of the food or its intended use. We understand how a reader might interpret proposed §§ 1.906 and 1.908 to mean that vehicles must be maintained and operated to always preclude food from becoming filthy, putrid, decomposed or otherwise unfit for food during transport, and that all food, including, for example, materials destined for rendering, that become filthy, putrid, decomposed or otherwise unfit for food as the result of transportation operations are adulterated. We, therefore, have revised § 1.906(a), (b), and (d), and § 1.908(a) to state that the relevant requirements for transportation vehicles, equipment and operations take the intended use of a vehicle or equipment into account and that the intent of these requirements is to prevent food from becoming unsafe, *i.e.*, adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act, during transportation. Therefore, we would not regard a transportation vehicle used to haul materials destined for rendering, *e.g.*, viscera, offal, trimmings from slaughter operations, to be operating under insanitary conditions, given that the vehicle's intended use is to haul materials that will undergo further processing to make them suitable for animal consumption. We also would not regard rendering materials in transport to be adulterated for the same reason. However, we note that those engaged in transport of materials destined for rendering should consider whether previous cargo that could cause the material to be unsafe due to potential chemical contamination is a relevant consideration.

We also recognize that provisions in §§ 1.906 and 1.908 of the proposed rule that refer to the need, under certain circumstances, for temperature control of food during transport to prevent the "rapid growth of undesirable microorganisms" are used without appropriate consideration of the intended use of the food, *e.g.*, it is intended to undergo further processing, and also suggest that any food in transportation in which undesirable microorganisms are present is adulterated. The proposed provisions further suggest that vehicles or transportation equipment that allow these conditions to prevail are insanitary for transportation purposes. We, therefore, have revised §§ 1.906(c) and 1.908(a)(3)(iii) in this final rule to state that these requirements are applicable to food that requires temperature control for safety during transportation. Unless otherwise stated, we use the phrase "food that requires temperature control for safety" in this rule to mean that such temperature control is needed to prevent the food from becoming unsafe during transportation. Therefore, we would not regard an unrefrigerated transportation vehicle used to transport bulk materials destined for rendering to be in violation of this rule because the vehicle's intended use is to transport materials that do not require temperature control because they will undergo a subsequent heat processing treatment to destroy pathogens. We also would not regard rendering materials in transport, *e.g.*, viscera, offal, trimmings from slaughter operations, to be adulterated for the same reason.

As we discuss in our response to Comment 130, regarding revisions we have made to proposed § 1.908(a)(3), we are also clarifying that, under this rule, the consideration of the type of food and its stage in the relevant production cycle are relevant in determining the necessary sanitary conditions and controls for any given transportation operation.

(Comment 90) One comment asks us to exempt equipment used for transporting fruit and vegetable culls, for deposit into pastures as food for grazing animals, from the bulk vehicle requirements of this rule. It notes that Florida fresh citrus packinghouses often load open-air dump trucks or dump trailers with culls for deposit onto the ground of local pastures. The cattle eating the culls are grazing animals and regularly feed from the ground. A similar comment asks us to exempt transportation operations that use certain classes of vehicles to transport raw and processed agricultural commodities, as well as feed and feed ingredients, from this rule at the outset to avoid a deluge of waiver petitions that this segment of the food transportation industry would otherwise submit to us for our consideration. This commenter singles out, for example, the use of shuttle trains and privately owned railcars that are dedicated exclusively to hauling grains and oilseeds as the types of transportation operations that it believes should be exempt from the rule. The comment also notes that animal feed and feed ingredient manufacturers often use their own dedicated truck fleets to haul large quantities of bulk and bagged products directly to farms and livestock and poultry operations. The commenter believes that these types of bulk vehicles and transportation equipment should be exempt from this rule because they pose limited risks for cross-contamination because SOPs for sequencing and cleaning-out these vehicles are already followed by these firms in order to comply with FDA's existing regulations for medicated animal feed.

(Response 90) As we discuss in Comment 75, we have added a provision to this final rule excluding human food byproducts transported for use as animal food without further processing from coverage by this rule. Therefore, transportation operations for fruit and vegetable culls, for deposit into pastures as food for grazing animals, are not subject to this rule.

We do not agree that the other types of vehicles described in these comments, or the transportation operations in which they are used, should be exempt from this rule. The requirements we are establishing for vehicles and transportation equipment, as we explained in our response to the previous comment, require that vehicles and transportation equipment be designed, maintained, and stored to prevent food from becoming adulterated during transportation under the vehicles' intended uses. These requirements are not burdensome and are appropriate even for vehicles used in operations where the risk of food adulteration is low.

Finally, we note in response to the comment that bagged animal feed and bagged animal feed ingredients are exempt from this rule. These items fall outside of the scope of "transportation operations" (as defined in § 1.904) that are subject to the rule because they are food completely enclosed by a container that does not require temperature control for safety.

(Comment 91) A few comments ask us to address the appropriate sanitary conditions for the use of wood pallets. One comment observes that wood is a porous material and therefore is vulnerable to water absorption and potential contamination, but asserts that as long as the food is in appropriate containers and does not come into direct contact with wood pallet surfaces, the opportunity for contamination is slight. Another comment asserts that the pallet conditions that we described as being insanitary in the proposed rule are too restrictive for animal feed transport and allow an FDA inspector too much subjectivity in determining whether a pallet is fit for its intended use.

(Response 91) Pallets need to be maintained so that they do not pose a risk of contaminating food during transportation or of compromising the integrity of the food containers that are supported by the pallet. For example, where the intended use of the pallet is such that food would be in direct contact with the wooden surface of the pallet, we expect that pallets would be used only to the extent they are cleanable and unlikely to support conditions that may make the food unsafe. (See Comment 88). In addition, pallets should not have jagged edges that protrude into the carrying surface in a way that could damage the product being shipped, *e.g.*, wood splinters that could puncture food containers.

(Comment 92) One comment asks us to amend the rule to allow railcars currently in use to remain in use until they are retired from service. The comment states that the absence of recent food safety incidents involving the rail transportation of food demonstrates that the design of railcars currently used in food transportation operations is adequate.

(Response 92) There are no provisions in this rule that would require a railcar currently in use to be removed from service, as long as its condition permits the safe transport of food in accordance with established industry practices. If a railcar is in a condition not suitable for such use, we would expect that the railcar provider would take that car out of service for refurbishment or that the shipper would refuse to use the car if it is offered for food transport.

(Comment 93) A few comments state that the term "adequately cleanable" used in proposed § 1.906(a) is vague. One comment asserts that it fails to provide any discernable benefit to food transporters in preventing food contamination.

(Response 93) As we state in our response to Comment 49, the term "adequate" is a long-standing term that we defined in its current form when we first established cGMP requirements for the manufacturing, packing, and holding of human food. We are using the terms "adequate" and "adequately cleanable" to provide flexibility for shippers, loaders, carriers, and receivers to comply with the requirements of this rule in a way that is both effective for purposes of preventing the adulteration of food during transport and most suitable for their particular operations.

(Comment 94) One comment states that we should recognize that not all transportation equipment needs to be cleaned before being used. The comment observes that cleaning wooden pallets can do more harm than good if proper precautions are not followed to prevent mold growth from moisture. The commenter notes that while it may be appropriate to expect water-based cleaning of certain types of transportation equipment, like hoses, for example, between every use, these kinds of cleaning practices should not be used for wooden pallets. The comment states that a visual inspection of pallets for cleanliness and suitability is sufficient to demonstrate that the pallets are acceptable for use and that the "adequately cleanable" standard for pallets should focus on the dry removal of debris like dust and dirt, when necessary.

(Response 94) We agree that there are circumstances under which some transportation equipment would not need to be cleaned before each use and that pallets that are adequately clean for their intended use do not necessarily need to be cleaned after each use. However, when the cleaning of vehicles and transportation equipment is necessary for a transportation operation to meet the requirements of this rule, we would expect that appropriate cleaning practices will be followed. We address our principal concerns about the use of pallets in our response to Comment 91.

2. Proposed § 1.906(b)

We proposed to require that vehicles and transportation equipment be maintained in such a sanitary condition as to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety as explained in responses to comments below, we have finalized this provision to require that vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(Comment 95) One comment states that this rule should explicitly distinguish between the terms "sanitize" and "clean" with respect to the intended use of the food being transported. The comment states that human food should be transported using equipment and vehicles that have been "sanitized" to prevent illness while a "clean" vessel is acceptable for the transport of animal feed.

(Response 95) We did not define the terms "sanitize" or "clean" in the proposed rule and we decline the commenter's suggestion that we do so in this final rule. Section 1.906(b) states that vehicles and transportation equipment must be maintained in a "sanitary condition." We do not consider "sanitary condition" to be synonymous with "sanitize." We consider "sanitary condition" to be a state of cleanliness. The term "sanitize" is associated with the reduction of potentially harmful microorganisms. Section 1.906(b) further states that the requisite sanitary conditions of vehicles and transportation equipment are to be determined by the "intended use" of the vehicles and equipment in order "to prevent the food they transport from becoming unsafe during transportation operations." Accordingly, as we state in our response to Comment 2, we recognize that the applicable sanitary transportation practices may vary depending on the types of food that are being transported. More stringent practices, for example, that might be necessary to ensure the sanitary transportation of one type of food, *e.g.*, human food or pet food, might not be necessary to ensure the sanitary transportation of a different category of food, *e.g.*, animal feed. Our response to Comment 2 discusses revisions we have made to §§ 1.906 and 1.908 to clarify this point. However, whether the transportation operation involves human food or animal feed, the responsible persons under this rule must use all necessary sanitary transportation practices, given their circumstances, to prevent the food from becoming unsafe.

(Comment 96) One comment states that proposed § 1.906(b)'s requirement that vehicles and transportation equipment, such as hoses and pumps, be maintained in a "sanitary" condition is too ambiguous. The comment asks what it means for vehicles and equipment to be clean or sanitary, how we expect firms to meet this regulatory requirement, and what other types of transportation equipment we anticipate will be subject to this provision. The comment asserts that under certain circumstances, animal feed for livestock can still be protected from becoming unsafe even if the equipment used to transport it is not sanitary, clean, or washed out prior to shipment. The comment states, for example, that a firm can use dedicated equipment, product sequencing, and equipment flushing with water or another appropriate fluid followed by blowing the lines clear. Another comment states that railway hopper cars and semi-trailers used for transporting feed ingredients are not always dedicated to a single ingredient, but rather frequently are also used to haul RACs. This comment notes that, as a matter of current industry practice, cleaning between feed ingredient and RAC loads is minimal because there is an assumption that minor co-mingling of different plant materials does not result in adulteration or otherwise present health hazards.

(Response 96) We are requiring in § 1.906(b) that vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent food from becoming unsafe during transportation operations. We are not prescribing, in this rule, methods (such as washouts) for the cleaning and maintenance of vehicles and equipment, nor are we establishing required intervals for cleaning operations. Firms may employ any cleaning procedures and intervals that meet the requirements of this rule.

(Comment 97) One comment states that the term "sanitary" as used in proposed § 1.906(b), and throughout the rule, is misleading because its general meaning infers a standard that exceeds the common understanding of the term "clean." The comment states that transportation equipment and containers for animal feed for livestock do not need to be "sanitary," but clean enough so as to prevent adulteration of the feed. The comment suggests that we delete the word "sanitary" from the rule except when we refer to the transportation requirements for human or pet food.

(Response 97) We decline to remove, or otherwise limit the use of, the word "sanitary" from this rule. We have not defined this term to mean "beyond clean" and our use of this term in the rule is not ambiguous. As we note in our response to Comment 95, we consider the term "sanitary" to be a state of cleanliness and we do not consider the term "sanitary" to mean that vehicles and transportation equipment necessarily must be "sanitized" to ensure that food is not rendered unsafe during transportation operations. We use the word "sanitary" in §§ 1.906 and 1.908 as it would apply to the conditions and controls employed for transportation operations, vehicles, and equipment to ensure that food will not be rendered unsafe during transportation. This is consistent with our responsibilities under section 7202 of the 2005 SFTA, which states that we shall, by regulation, require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food unsafe.

Finally, as we also state in our response to Comment 2, we agree that this rule should more clearly recognize that sanitary transportation practices may differ depending on the types of food being transported, for example, human food versus animal food. Our response to that comment discusses revisions we have made to §§ 1.906 and 1.908 to clarify this point.

(Comment 98) One comment asks us to acknowledge that polymerized oil residues that form on the interior steel surfaces of rail tanker cars during the repeated hauling of edible oils for processing into feed ingredients do not adulterate the oil. The comment notes that these residues only present food quality concerns and are removed by filtration and further processing.

(Response 98) We agree. Residues that may form during edible oil transportation operations as described in the comment, which we would expect to be removed during further processing steps, are constituents of the oil which are not toxic by nature and do not make the food unsafe.

3. Proposed § 1.906(c)

We proposed to require that vehicles and transportation equipment that are used in transportation operations for food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation must be designed, maintained, and equipped, to maintain the food under temperature conditions that will prevent the rapid growth of undesirable microorganisms. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety and to add flexibility with regard to the approach to monitoring temperature control as explained in responses to comments below, in this final rule we have revised proposed § 1.906(c), with consideration of the provisions of proposed § 1.906(d), such that final § 1.906(c) requires that vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped, as necessary, to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.

(Comment 99) Several comments ask that we acknowledge that means other than refrigerated vehicles can be used to keep food adequately cold during transport. These include the use of ice, dry ice, insulated coolers, and cooler totes. Another comment asks us to clarify that firms are not required to purchase cold foods from vendors with refrigerated vehicles, that is, the comment seeks clarification that firms can purchase cold foods from vendors who use means other than refrigerated vehicles for purposes of maintaining necessary temperature control of food products during transport.

(Response 99) There is no requirement in this rule that foods subject to temperature control requirements must be transported in refrigerated vehicles or must be purchased from vendors with refrigerated vehicles. The use of the alternative methods described in this comment for keeping food cold during transport are acceptable under this rule if the vehicles, for example, catering trucks and commissary delivery vehicles, equipment, and transportation operations comply with the requirements of §§ 1.906 and 1.908.

4. Proposed § 1.906(d)

We proposed to require that each freezer and mechanically refrigerated cold storage compartment in vehicles or equipment used in transportation operations for food that can support the rapid growth of microorganisms in the absence of temperature control during transportation must be equipped with an indicating thermometer, temperature measuring device, or temperature recording device to show the temperature accurately within the compartment. We have removed § 1.906(d) as proposed from the rule.

(Comment 100) A few comments address this proposed requirement. A participant at one of the public meetings we held on the proposed rule stated that we should require a temperature recording device for all transport vehicles that use refrigeration. One submitted comment states that it should not apply to a carrier if the shipper has provided its own device or relies on measures such as ice packs to maintain adequate temperature control. Another comment asks us to explicitly permit the use of hand-held temperature recording devices as an alternative to devices installed in or on a cold storage cooler. A few comments assert that low cost, time-temperature indicators are generally adequate for temperature monitoring purposes and that we should not require the use of expensive installed recording devices. A comment from the seafood industry states that ensuring continuous temperature control during the entire transit time requires the use of time-temperature recording devices (or the effective use of ice or other cooling media) and that indicating thermometers and temperature measuring devices are inadequate because they do not provide continuous documentation of temperature readings.

(Response 100) We agree that there are a number of effective methods for monitoring temperature control during food transportation, some of which do not require the permanent installation of a device in the compartment. We reconsidered this proposed provision and have determined that persons subject to this rule should be able to use any effective means to monitor temperature control, such as those suggested by the comments, and that it is not necessary to retain this proposed requirement. Therefore, we have removed this provision from this final rule.

(Comment 101) One comment also states that the proposed rule did not discuss the need for temperature indicating devices to be checked for accuracy and calibration.

(Response 101) As we stated in our response to Comment 100, we have removed the requirement that vehicles and transportation equipment be equipped with a temperature indicating device from this final rule. Therefore, there is no need to establish temperature measuring equipment calibration requirements in this final rule.

5. Proposed § 1.906(e)

We proposed to require that vehicles and transportation equipment must be stored in a manner as to prevent the vehicles or transportation equipment from harboring pests or becoming contaminated in any other manner that could result in food for which they will be used becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during transportation operations. Consistent with a decision to more narrowly focus this rule on adulteration linked to food safety as explained in responses to comments that follow (particularly see Comment 89), in this final rule we are requiring that vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations. In the final rule, this provision is redesignated § 1.906(d) consistent with the removal of proposed § 1.906(d).

(Comment 102) One comment notes that some end-users store pallets used in transportation operations out-of-doors prior to use. The comment argues that end-users' pallet storage practices are just as, if not more, important for food safety than the programs and processes followed by pallet manufacturers and that pallets must be stored in an area with adequate light and airflow to prevent the formation of mold on the pallets.

(Response 102) We have established requirements for the storage of transportation vehicles and equipment, including pallets, in § 1.906(d). The outdoor storage of pallets is permissible if the pallets meet the requirements of this section when they are used in transportation operations, *i.e.,* they must be in such a condition that they will not cause the food that will be placed on them to become unsafe. When pallets are used to hold fully packaged foods, no or minimal cleaning may be necessary after outdoor storage. However, when they are used in such a way that ready to eat food comes into contact with the pallet, such as when they are used to hold some open mesh crates of produce, cleaning may be necessary after outdoor storage, especially if visible contaminants are present.

(Comment 103) One comment states that railroad carriers shouldn't be responsible for how a railcar is stored at a third-party facility and asks us to clarify that the current industry practice of storing railcars on spur tracks and in rail yards is acceptable.

(Response 103) We agree that the storage of railcars on spur tracks and in rail yards is acceptable if such storage meets the requirements of this rule (*e.g.,* it does not become infested with rodents in such a way that subsequent cleaning will be ineffective). In most cases, empty railcars will be cleaned by or for the shipper after such storage, before use in holding food. However, if a railcar is stored in a manner that can lead to food that is subsequently loaded onto it becoming unsafe, that food may be rendered adulterated. Determining who is responsible for such adulteration would be performed on a case-by-case basis, according to the specifics of the situation. As discussed in section IV.E.2., a shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. These measures may be accomplished by the shipper or undertaken by the carrier or a third party.

E. What requirements apply to transportation operations? (§ 1.908)

In table 8, we describe revisions to proposed § 1.908 and following the table we respond to comments related to these provisions.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.908(a)	General Requirements	
1.908(a)(1)	Requirements apply to all shippers, carriers, loaders, and receivers and a person may be subject to these requirements in multiple capacities.	Added "loaders" to the provision and moved statement out of individual definitions that a person could be, for example, both a shipper and a carrier.
1.908(a)(2)	Ensuring compliance with requirements must be assigned to competent supervisory personnel.	No change.
1.908(a)(3)(i)–(iii)	Transportation operations must be conducted so as to prevent food from becoming unsafe, including taking measures such as segregation, isolation, and packaging to separate foods; taking protective measures for food in bulk vehicles or not completely enclosed in a container from contamination and cross contact; and ensuring that food that requires temperature control for safety is transported under adequate temperature control.	Replaced "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health" with "unsafe" in 1.908(a)(3) and replaced description of "food that can support the rapid growth of undesirable microorganisms in the absence of temperature control" with "food that requires temperature control for safety" in 1.908(a)(3)(iii).
1.908(a)(4)	Specify relevant factors (*e.g.,* animal food vs. human food, raw material vs. finished food) in determining the necessary conditions and controls for the transportation operation.	New provision.
1.908(a)(5)	Specify that shippers, receivers, loaders and carriers which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated, written procedures that ensure the sanitary transportation of food consistent with the requirements of this section.	New provision.
1.908(a)(6)	If a covered entity becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe the food shall not be sold or otherwise distributed until it is determined that the temperature deviation or other condition did not render the food unsafe.	New general requirement, which was previously assigned to the receiver in consultation with the carrier and the shipper.
1.908(b)	Requirements applicable to shippers	
1.908(b)(1)	Requires that the shipper provide in writing to the carrier and, when necessary, the loader all necessary sanitary specifications for the carrier's vehicle and transportation equipment to prevent the food from becoming unsafe. The shipper may take other measures in accordance with 1.908(b)(3).	Added "loaders" to the provision and the clause that a shipper may take other measures in accordance with 1.908(b)(3). Added that a one-time notification of the sanitary specifications shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported.
1.908(b)(2)	Shipper must specify in writing to the carrier, except a carrier who transports food in a thermally insulated tank, and when necessary the loader an operating temperature including, if necessary, the pre-cooling phase for a food requiring temperature control for safety. Shipper may take other measures in accordance with 1.908(b)(5) to ensure adequate temperature control.	Was proposed as 1.908(b)(3) and required the shipper of a "Time/temperature control for safety" (TCS) food to provide information on the temperature conditions necessary for transport in writing to the carrier to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being injurious to health. The revised provision focuses on the food safety concerns with temperature control.
1.908(b)(3)	Shipper must develop and implement written procedures adequate to ensure that vehicles and equipment are in appropriate sanitary condition for the transport of food. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement.	New provision.
1.908(b)(4)	Shipper of food transported in bulk must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement.	New provision.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.908(b)(5)	Shipper of food that requires temperature control for safety must develop and implement written procedures to ensure the food is transported under adequate temperature control. Measures to implement the procedures may be done by the shipper or another party under the terms of a written agreement and must include measures equivalent to those specified for carriers under 1.908(e)(1)–(3).	New provision.
1.908(c)	Requirements applicable to loaders	
1.908(c)(1)	Before loading food not completely enclosed by a container, the loader must determine, based as appropriate on shipper specifications, that the vehicle or transportation equipment is in appropriate sanitary condition (*e.g.*, adequate physical condition, free of visible evidence of pest infestation, and previous cargo that could make the food unsafe).	This new requirement for loaders is similar to requirements that were proposed for the shipper at proposed 1.908(b)(2), but the shipper may not be on site. Proposed 1.908(c)(1) was about access to handwashing facilities and has been removed from the rule.
1.908(c)(2)	Before loading food requiring temperature control for safety, the loader must verify, considering as appropriate the shipper specifications, that each mechanically refrigerated cold storage compartment or container is adequately prepared, including proper precooling if necessary.	This new requirement for loaders is similar to proposed 1.908(c)(2), which required shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control to load and unload under conditions that would not support such growth. This new loader requirement is also similar to proposed 1.908(b)(4) which required shippers to verify that each mechanically refrigerated cold storage compartment or freezer has been properly pre-cooled.
1.908(d)	Requirements applicable to receivers engaged in transportation operations. Upon receipt of a food requiring temperature control for safety, receivers must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle, or smelling for off-odors.	This provision specifically for receivers is new, resulting from comments and our understanding that receivers would typically make a determination that a shipment may have been subject to significant temperature abuse. Proposed 1.908(d) contained the provisions applicable to carriers, which are finalized as 1.908(e) in this rule.
1.908(e)	Requirements applicable to carriers	
1.908(e)(1)	Per an agreement with the shipper that the carrier is responsible, the carrier must ensure that vehicles and equipment meet the shipper's specifications in accordance with 1.908(b)(1) is otherwise appropriate to prevent the food from becoming unsafe.	Similar to proposed 1.908(d)(1) except "filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health" has been replaced with "unsafe" per our focus on adulteration linked to food safety.
1.908(e)(2)	Per an agreement with the shipper that the carrier is responsible, upon completion of the transport and if requested by the receiver, provide the operating temperature specified by the shipper and, if requested by the shipper or receiver, demonstrate that temperature conditions were maintained during transport consistent with shipper specifications.	Similar to proposed 1.908(d)(2) which would have required the carrier to demonstrate to shippers and, if requested, to the receiver that temperature conditions were maintained consistent with shipper specifications. The revisions in final 1.908(e)(2) are consistent with our new provision in 1.908(d) that receivers take steps to adequately assess that the food was not subjected to significant temperature abuse.
1.908(e)(3)	Per an agreement with the shipper that the carrier is responsible, carriers must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper before offering a vehicle for transport of food requiring temperature control for safety.	Similar to proposed 1.908(d)(3) except that the focus is on food requiring temperature control for safety rather than foods that support the rapid growth of undesirable microorganisms, such as those that cause spoilage. The focus on food safety is also why the final provisions regarding pre-cooling have eliminated references to freezers, since it is likely that there would be significant quality defects with time/temperature abused frozen foods prior to the point at which they would become unsafe.
1.908(e)(4)	Per an agreement with the shipper that the carrier is responsible and if requested by a shipper, a carrier that offers a bulk vehicle must identify the previous cargo.	Similar to proposed 1.908(d)(4), which would have required the carrier to identify the three previous cargoes. We realized that requiring provision of three previous cargoes was not necessary for food safety and we heard in comments that a carrier may not have any previous cargo information in the normal course of its business. Therefore, our final provision specifies that this information must be provided by the carrier if it agrees to provide the information. Otherwise, the shipper is responsible for considering the sanitary requirements necessary to prevent food from becoming unsafe during transport.

TABLE 8—§ 1.908 WHAT REQUIREMENTS APPLY TO TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.908(e)(5)	Per an agreement with the shipper that the carrier is responsible and if requested by a shipper, a carrier that offers a bulk vehicle must provide information that describes the most recent cleaning of the vehicle.	Similar to proposed 1.908(d)(5), which would have required the carrier to describe the most recent cleaning of the bulk vehicle to the shipper. We heard in comments that a carrier may not have any previous cleaning information in the normal course of its business. Therefore, our final provision specifies that this information must be provided by the carrier if it agrees to provide the information. Otherwise, the shipper is responsible for considering the sanitary requirements necessary to prevent food from becoming unsafe during transport.
1.908(e)(6)(i)—(iii)	Carriers must develop and implement written procedures that (i) specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment to maintain them in appropriate sanitary condition, (ii) describe how it will comply with the temperature control requirements in 1.908(e)(2), and (iii) describe how it will comply with the provisions for use of bulk vehicles in 1.908(d)(4) and (d)(5).	No change from proposed 1.908(d)(6), except to change references to paragraph (d) to (e).

1. General Requirements (Proposed § 1.908(a))

We set forth in proposed § 1.908(a) general provisions and requirements applicable to transportation operations.

(Comment 104) We received many comments expressing concern that the proposed rule did not sufficiently recognize that practices for the transportation of raw materials may differ from those for finished food products, and that practices for the transportation of animal feed may differ from those used to transport pet food and finished human food.

(Response 104) We agree with the comments and have added new § 1.908(a)(4) to make it clear that the type of food *e.g.,* animal feed, pet food, human food, and its' production stage *e.g.,* raw material, ingredient or finished food, are relevant to and must be considered in determining the necessary conditions and controls for transportation operations.

(Comment 105) One comment expresses concern about the potential for cross contamination during the transportation of RACs. The comment states that the cross utilization of any equipment, including transportation vehicles, should be conducted in a manner that does not subject RACs to contamination and that equipment used to transport any food products that are minimally processed and consumed raw should be subject to sanitary requirements tailored to ensure the safety of the products.

(Response 105) We agree that cross utilization of vehicles and equipment should not subject any food, including RACs, to cross contamination during transport. The provisions of § 1.906 require the design, maintenance and storage of vehicles and transportation equipment, to be such that they will not cause food to become unsafe during transportation operations. In addition, § 1.908(a)(3), which in part addresses the proper use of vehicles and equipment in transportation operations, requires that all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe.

a. Proposed 1.908(a)(1)

As previously discussed in the sections of this document related to the definitions of carrier, shippers and receivers, we have removed from these definitions the proposed sentence in each definition that stated that a party may serve in more than one capacity under this rule, *e.g.,* a carrier may also be a receiver or a shipper, if the person also performs the functions of those respective persons. While we affirm that these statements are valid, we have consolidated them into a new sentence at § 1.908(a)(1), which states that a person may be subject to these requirements in multiple capacities, *e.g.,* the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart.

b. Proposed 1.908(a)(3)

(Comment 106) One comment asserts that the requirements of this rule appear to duplicate warehousing and distribution requirements that appear in the FSMA preventive controls for human food rule, which require that food storage and transportation must be conducted under conditions that will protect against cross-contact and biological, chemical, physical, and radiological contamination of food, as well as against deterioration of the food and its container.

(Response 106) The preventive controls rule for human food requirements in 21 CFR 117.93 provide broad good manufacturing practice (GMP) standards for warehousing and transportation-related activities that occur within the context of warehousing and distribution operations of facilities engaged in the manufacturing, packing, and holding of human food. This rule is intended to be complimentary to those and other provisions of the Preventive Controls rules for human and animal food and establishes more detailed requirements for shippers, loaders, receivers, and carriers to use sanitary transportation practices to ensure that food is transported under conditions that will prevent it from becoming unsafe. This is FDA's only rule that addresses the transportation of food in an integrated manner from beginning to end by establishing the interactions that must occur between shippers, loaders, carriers, and receivers to ensure that sanitary food transportation practices are used by the food industry. It is also the only rule to which carriers are directly subject. Accordingly, this rule is not redundant, as asserted by this comment, because it expands on the transportation-related requirements contained in the GMPs.

(Comment 107) A few comments question the appropriateness of using the terms "under such conditions and controls necessary to prevent the food from becoming . . . decomposed or otherwise unfit for food" to describe requirements for transportation operations. The comments state that fresh fruits and vegetables are perishable food products and therefore by their very nature eventually enter the senescence stage and begin to degrade (decompose) after they are harvested. The comments further state that such foods can be in this stage during transportation without yet becoming unfit for food. These comments assert that we are confusing the concepts of food safety and food quality by including these terms in this rule. The comments state that the terms should be removed and that the final rule should be strictly limited to ensuring the safe transportation of human and animal food.

(Response 107) We acknowledge in our response to Comment 89 that we applied the language from section 402 of the FD&C Act in an overly broad manner in the proposed rule, so as to suggest, unintentionally, that any food in transport that is undergoing a natural process, *i.e.*, senescense, is per se adulterated under this rule. As we also note in our response to Comment 89, we have revised § 1.908(a) in this final rule to state that the intent of this provision is to prevent food from becoming unsafe. We would not regard perishable fruits and vegetables that are senescing during transport to be adulterated or unsafe.

(Comment 108) One comment encourages us to ensure that time/temperature control provisions of this final rule will complement related provisions contained in our seafood HACCP regulation.

(Response 108) Our intent in drafting this final rule is to make it compatible with the seafood HACCP rule, which does not include requirements applicable to carriers. Under the seafood HACCP regulation, receivers are required to ensure that transportation was performed under appropriate temperature control, where such control is necessary for the safety of the food. To accomplish this, receivers of seafood often request temperature monitoring information from the carrier upon receipt. As we discuss in our response to Comment 129, this rule should assist receivers of seafood products by requiring that, upon their request, carriers must provide the operating temperature specified by the shipper and demonstrate that it has maintained temperature conditions during the transportation operation consistent with that operating temperature.

c. Proposed 1.908(a)(3)(i)

We proposed to require that persons take effective measures, such as segregation or isolation, to prevent raw foods and nonfood items from contaminating other food products that might be shipped in the same load during transportation operations.

(Comment 109) One comment addressing proposed § 1.908(a)(3)(i) asserts that current industry practices ensure the adequate separation of ready-to-eat food items from raw foods and nonfood items through the use of packaging and impermeable barriers. The comment also states that our *Food Code* (Ref. 28) also considers packaging to be an adequate barrier for protecting food from contamination. Section 3–302.11 A. (4) of the *Food Code* states that "[f]ood shall be protected from cross-contamination by storing the food in packages, covered containers, or wrappings." The comment argues that because we acknowledged in the proposed rule that industry has developed practices that "ensure that food is adequately protected from contamination by raw food items on the same load," there is no need to include the "segregation and isolation" language in this rule. The commenter further stated, however, that if we retain this language in the final rule, we should revise it to clarify that this provision should not be interpreted as requiring the complete isolation of raw foods from ready-to-eat foods during transportation.

(Response 109) The 2005 SFTA mandates that we issue regulations to require that shippers, carriers, receivers and other persons engaged in the transportation of food use sanitary transportation practices to ensure that food does not become adulterated during transportation. We agree that both packaging, and segregation or isolation can be effective means of protecting food from contamination by raw foods or nonfood items in the same load. Therefore, we have revised proposed § 1.908(a)(3)(i) to include packaging as one of the examples of such preventive measures during transportation operations.

d. Proposed 1.908(a)(3)(ii)

We proposed to require that persons engaged in transportation operations take effective measures such as segregation, isolation, or other preventive measures such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

(Comment 110) One comment addressing proposed § 1.908(a)(3)(ii) asserts that persons who handle animal feed or raw feed ingredients without using gloves or washing their hands are not going to contaminate or adulterate food while engaged in loading, unloading, or transportation activities. The comment, therefore, asks us to exempt persons who handle animal feed from this provision.

(Response 110) This provision does not require that persons who handle animal feed or raw feed ingredients always wear gloves and/or wash their hands. These measures are provided only as examples of steps persons may take to meet the requirements of this rule. As proposed, § 1.908(a)(3)(ii) provides persons engaged in food transportation the flexibility to determine for themselves which measures are necessary to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. For this reason, we have not modified this section.

e. Proposed 1.908(a)(3)(iii)

We proposed to require persons engaged in the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation to follow transportation practices, including attention to temperature conditions, to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source.

(Comment 111) Several comments ask us to reconsider including temperature control requirements for non-TCS foods that require temperature control only for purposes of preventing spoilage and not for purposes of ensuring food safety.

One comment states that because there are no potential safety hazards associated with such non-TCS foods, strict transportation temperature control requirements are not warranted. One comment observes that we proposed to exempt facilities that hold completely packaged refrigerated food from the requirements of the proposed FSMA preventive controls rule for human food, with the exception of facilities that hold TCS food. Under the preventive controls rule, facilities that hold such TCS food are only subject to preventive controls requirements to provide appropriate temperature control for such food. The comment asserts that we should not impose more stringent requirements on the transportation of food than we require for the holding of food under the preventive controls rule. The comment asserts that this rule, therefore, should not apply transportation requirements for temperature control to non-TCS foods that require temperature control only for purposes of preventing spoilage.

One comment acknowledges that the language of the 2005 SFTA is somewhat different from the language FSMA in that it directs us to issue regulations that are meant to ensure that food is not transported under conditions that may render the food adulterated. The comment further notes that adulteration is broadly defined by the FD&C Act and can encompass issues such as food spoilage in addition to the narrower issue of food safety. However, this comment states that such considerations are already addressed by the FD&C Act's adulteration provisions in section 402, and notes that FDA has the discretion to implement the provisions of the 2005 SFTA in a manner consistent with a risk-based framework focused more narrowly on food safety risks.

Another comment states that while the temperature control provisions of this rule should not address non-TCS foods, it does not object to the inclusion of references in § 1.906 to the prevention of the rapid growth of undesirable microorganisms (which would include microorganisms that cause spoilage) with respect to the design and maintenance of vehicles and transportation equipment, and in § 1.908 with respect to conditions for loading and unloading food, because these provisions do not relate to the maintenance of temperature control during transportation.

(Response 111) We agree with the comments and explain in our response to Comment 89 that we have revised this rule to require temperature control only for foods that require temperature control for safety. Conversely, the temperature control requirements do not apply to food that is transported under temperature control for other reasons, for example, for marketability purposes, or to prevent spoilage of the food. In particular, we agree with the comment that stated that nonsafety considerations are already adequately addressed by the FD&C Act's adulteration provisions in section 402, and that we have the discretion to implement the provisions of the 2005 SFTA in a manner consistent with a risk-based framework focused more narrowly on food safety hazards.

We also have reconsidered whether to define a descriptive category for the type of food (*i.e.,* "Time/Temperature Control for Safety (TCS) Food") that would be subject to the temperature control provisions of this rule. We conclude that such a definition would serve no purpose because the revision we discuss in the preceding paragraph adequately designates the foods that would be subject to this rule's temperature control requirements. Therefore, we have removed the term "Time/Temperature Control for Safety (TCS) Food" in the definitions section of this final rule in § 1.904 and we have removed from this final rule the descriptive categories, "TCS and non-TCS," which appeared in § 1.908(b)(3) of the proposed rule.

The temperature control requirements of this rule apply to any food that requires temperature control for safety during transport, and foods in the latter category, though not subject to the temperature control requirements of this rule, are still subject to the adulteration provisions and other applicable provisions of the FD&C Act and applicable implementing regulations.

(Comment 112) One comment asks us to rewrite the temperature control provisions of this rule to clarify the requirements applicable to TCS and non-TCS foods. Other comments recommend that we establish temperatures for use by shippers in crafting instructions to be given to carriers, to prevent discrepancies in temperature control recommendations among shippers. Some comments also suggest that we should provide guidance to the transportation industry for temperature control that would include extensive lists of TCS and non-TCS foods. One of these comments states that clarifying temperature controlled food requirements and providing such guidance would have the added benefit of assisting regulators tasked with the responsibility of enforcing this rule. One comment asks us to establish a maximum transportation temperature of 45 degrees Fahrenheit for TCS foods.

(Response 112) We decline these requests. As we explain in our response to the preceding comment, we have removed the term "Time/Temperature Control for Safety (TCS) Food" from the definitions section of this final rule in § 1.904, and we have removed from this final rule the descriptive categories "TCS and non-TCS," which appeared in § 1.908(b)(3) of the proposed rule. We have replaced the definition with the concept of "foods that require refrigeration for safety."

Because of the vast diversity of human and animal food types, FDA does not have the resources to compile exhaustive lists of foods that require or do not require temperature control for refrigeration nor a list of the appropriate temperature controls for foods. Such a task is made even more daunting because similar foods produced by different manufacturers may have different temperature control requirements, because of differences in formulation. We expect shippers of food to be aware of whether the foods that they are shipping require refrigeration for safety, either because they are the manufacturer of the food or are otherwise knowledgeable about the food safety attributes of the food, or because they have obtained such information from the manufacturer or another knowledgeable person. The Preventive Controls rules for human and animal food require the manufacturer of a food to consider the transportation needs of foods that they manufacture when they develop their food safety plans.

Furthermore, as we explain in our response to Comment 129, we are no longer requiring shippers to specify temperatures to carriers that would be regarded as critical limits for food safety purposes. In many circumstances, the shipper is required to specify an operating temperature to the carrier, and the food is not necessarily unsafe or otherwise adulterated if that temperature is exceeded during transportation. Operating temperatures are generally set to allow for refrigeration compartment temperature fluctuations due to normal activities such as defrosting and opening and closing doors. They also are often set to minimize product deterioration, which is usually a more restrictive requirement than food safety. Regulatory limits for operating temperatures would need to integrate all of these factors for the diversity of foods and operations on the market. We will consider establishing guidance in the future for operating temperatures for the transportation of foods that require temperature control, should the need arise.

We disagree with the suggestion that we should establish a maximum transportation temperature of 45 degrees Fahrenheit for TCS foods. As we explain in our response to Comment 129, we have established requirements, as revised in this final rule, that would preclude the sale or distribution of any food that upon receipt presents an indication of a possible temperature control material failure during transport, unless it can be determined that the temperature deviation has not rendered the food unsafe. We conclude that this is an appropriate science-based approach to apply when assessing whether a potentially significant temperature deviation has occurred during transport because it provides for consideration of all significant factors, *e.g.,* the ability of the specific food to support pathogens that are reasonably likely to be present in the food, and the duration of the temperature deviation, rather than simply whether a temperature limit was exceeded. Furthermore, allowing a TCS food to be transported at temperatures up to 45 degrees Fahrenheit would not provide appropriate temperature control for some TCS foods, which may have to be transported at lower temperatures to ensure the safety of the food, *e.g.*, some vacuum packaged fish.

(Comment 113) We requested comment in the proposed rule regarding whether, unlike the proposed regulation, the final regulation should apply to the transportation by farms of TCS RACs, which require time/temperature control for food safety purposes, *e.g.*, raw seed sprouts. One comment offers the view that we should not include transportation by farms of TCS RACs in this regulation and that the industry's current best practices, which were not identified in the comment, sufficiently protect TCS RACs from adulteration during transportation.

(Response 113) As we discuss in our response to Comment 111, we have removed the term "Time/Temperature Control for Safety (TCS) Food" from the definitions section of this final rule in § 1.904, and we have removed from this final rule the descriptive categories "TCS and non-TCS," which appeared in § 1.908(b)(3) of the proposed rule. Nonetheless, we received no comments that provided any information that changed our tentative conclusion to exclude from coverage TCS RACs when they are being transported by farms. Consequently, we have made no change in that regard. However, when such a RAC is being transported by a person other than a farm, it is subject to the applicable provisions of §§ 1.906 and 1.908 of this rule that require transportation temperature control when it is necessary to prevent the food from becoming unsafe.

(Comment 114) One comment asks us to acknowledge that fresh whole apples, pears, and cherries are transported under temperature control exclusively for quality purposes. The comment also asks us to acknowledge that we regard these fruits as being comparable to bananas, which we stated in the proposed rule are not subject to proposed § 1.908(a)(3)(iii) because there is no risk they will become adulterated if they are transported under conditions that are not temperature controlled. Another comment asks us to provide more examples of foods that would not be subject to proposed § 1.908(a)(3)(iii), and suggests that these additional examples should include potatoes intended for processing into potato chips and chocolate and dairy based seasoning ingredients. The comment also asks us to train FDA inspectors to understand the circumstances under which foods would or would not require temperature control under this rule. Another comment asks us to exclude nuts, which are sometimes refrigerated during transport for quality purposes, from the scope of proposed § 1.908(a)(3)(iii).

(Response 114) This rule only requires temperature control during transportation when it is necessary to prevent the food from becoming unsafe. This rule does not establish requirements for the use of temperature control during food transportation for any other purpose, such as for marketability purposes, or to preclude the spoilage of food subject to this rule. We will ensure that our inspectors understand which factors generally distinguish foods that require temperature control to prevent the food from becoming unsafe from other foods that are transported under temperature control for quality purposes. As discussed earlier in this document, shippers are responsible for determining whether a food is subject to the temperature control provisions of this rule, because they require temperature control for safety. Whole, fresh apples, cherries, pears and potatoes are all examples of foods that generally do not require temperature control for safety. As we state in our response to Comment 112, we do not have the resources to provide an exhaustive list of foods that are transported under temperature control only for marketability purposes.

(Comment 115) One comment asserts that the temperature control provisions of this rule do not apply to the transportation of refined fats and oils. The comment notes that the presence of temperature specifications in transportation documents such as bills of lading is related to quality and performance attributes of the refined fats or oils, and therefore should not serve as a basis for extending this rule's temperature control provisions to the transportation of refined fats and oils. The comment also notes that refined fats and oils are manufactured in closed systems and that the final product does not support the growth of undesirable microorganisms.

(Response 115) We recognize that there may be occasions where temperature control is necessary for maintaining certain product attributes such as product quality, but not to prevent the food from becoming unsafe, as is the case, generally, for refined fats and oils. If temperature control is not required to prevent the food from becoming unsafe during transportation, the temperature control provisions of this rule do not apply to those transportation operations.

2. Requirements Applicable to Shippers Engaged in Transportation Operations (Proposed § 1.908(b))

a. Proposed § 1.908(b)(1)

We proposed to require that the shipper must specify to the carrier, in writing, all necessary sanitary requirements for the carrier's vehicle and transportation equipment, including any specific design requirements and cleaning procedures to ensure that the vehicle is in appropriate sanitary condition for the transportation of the food, *e.g.*, that will prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a) of this rule.

(Comment 116) One comment states that proposed § 1.908(b)(1) should be revised so that it would apply only to requirements for the carrier's vehicle and transportation equipment that exceed the carrier's basic obligation to provide vehicles and transportation equipment that are clean, appropriate, and in safe condition for transportation of the food intended to be shipped.

(Response 116) As we state in our response to Comment 119, we are aware that written information sharing between shippers and carriers currently is a routine part of the working relationship between these entities. We are retaining § 1.908(b)(1) to ensure that all necessary requirements for the preparation of a vehicle or transportation equipment are communicated to carriers. However, this provision allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of this rule. We understand that a shipper could reasonably determine that it is not necessary to specify any procedures that are commonly understood by carriers such as those described by the comment.

We have, however, modified this provision in several ways. First, because we have added a definition of loader, in response to comments that urged that we account for activities performed by the person loading a vehicle when that person is not also the shipper, receiver or carrier (see Comment 70). We recognize that there will be times when the shipper must provide instructions to the loader in addition to the carrier, *e.g.*, instructions about any special sanitary conditions to look for during the a preloading inspection. For this reason, we have included the loader as a person to whom the shipper must provide instructions about the sanitary specifications for the carrier's vehicle, when necessary. Second, we have changed the word "requirements" to "specifications" in two places in this provision. We believe that this word better conveys the idea of conditions set out by the shipper to the carrier and loader, and is less likely to be confused with regulatory requirements of the rule. Third, we have changed the proposed phrase "prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health" to "prevent the food from becoming unsafe" for consistency with our previously stated objective of focusing this final rule on food safety only. Finally, we have prefaced the requirement with the phrase, "unless the shipper takes other measures in accordance with paragraph (b)(3) of this section, to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food." We have added this language in response to comments from the railroad industry (see Comment 53) that stated that they generally do not have a relationship with shippers whereby the shipper provides them with instructions relative to the sanitary condition of the railcar that they are to deliver. Our intent is that the language will establish the requirements of § 1.908(b)(1) as the default arrangement whereby the shipper ensures that the vehicle and equipment meet appropriate sanitary conditions by providing instructions to the carrier and, when necessary, the loader, while also allowing for alternative arrangements (*e.g.,* whereby the shipper personally ensures that the specifications are met), when that is consistent with the shipper's written SOPs, as provided for in § 1.908(b)(3). We expect that many shippers that work with rail carriers will elect this latter approach, relieving them of the necessity to instruct the carrier about the necessary sanitary conditions for the railcar.

(Comment 117) One comment states that while obtaining written specifications from a shipper about vehicle and equipment sanitation, cleanliness procedures, and temperature requirements is an industry best practice, it is not always feasible or practical. The comment asserts that there is no evidence to suggest that shipper specifications communicated verbally to the carrier instead of in writing create a higher food safety risk.

(Response 117) We continue to assert that written specifications are consistent with industry best practice and are necessary to avoid confusion about the responsibilities of the various parties engaged in transportation operations. Such records are also valuable to assist FDA and other regulatory agencies in their verification role.

(Comment 118) One comment singles out proposed § 1.908(b)(1) as an example of a requirement for which we should afford firms flexibility and latitude to vary the content and level of detail contained in written specifications. The comment states that flexibility is needed, for example, to account for variations in the type of food type being transported, packaging, equipment, the transportation environment, and the shipper's experience with the carrier.

(Response 118) We acknowledge that numerous, variable factors can affect the types of procedures that are required to prepare a vehicle or equipment to be offered to a shipper. For example, the nature of the previous cargo transported in a tanker truck might affect the type of cleaning procedure that would need to be followed to prepare the tanker truck for its next cargo. We would expect that these types of factors will affect the content and degree of detail contained in written specifications that shippers would provide to carriers and loaders under § 1.908(b)(1). Nevertheless, the shipper must provide specifications to the carrier, and loader as necessary, that are adequate to enable them to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transportation of the food, *e.g.,* that will prevent the food from becoming unsafe during the transportation operation.

(Comment 119) One comment asserts that the food transportation industry already has proven its ability to manage successfully information sharing between shippers and carriers through, for example, contractual agreements. The comment also asserts that proposed § 1.908(b)(1) will only add an additional, unnecessary layer of recordkeeping that will not add to the goal of feed safety, and that § 1.908(b)(1) seems unnecessary, given that we require carriers to inspect transportation vehicles prior to loading. Finally, the comment states that we should provide clarification regarding how frequently information must be shared between shippers and carriers if we decide to retain this provision.

(Response 119) As this comment observes, written information sharing between shippers and carriers engaged in food transportation already is a part of the routine working relationship between these entities. We do not envision that § 1.908(b)(1) would require additional information sharing above and beyond that which routinely occurs and is necessary for purposes of enabling a carrier to offer a vehicle or transportation equipment in appropriate sanitary condition for the transportation of the food. Furthermore, the requirement in proposed § 1.908(b)(2), that a vehicle or transportation equipment be inspected prior to loading prescribed cargoes, is a verification step that also reflects existing best practice and does not obviate the need for shippers to provide specifications to carriers that are adequate to enable a carrier to offer a vehicle or transportation equipment in appropriate sanitary condition for the transportation of the food. Therefore, we are retaining this requirement.

However, as we note in our response to Comment 124, we have added language to § 1.908(b)(1) stating that a one-time notification by a shipper to a carrier, and, when necessary, to a loader, shall be sufficient, unless there is a factor, *e.g.,* the food or the conditions of shipment change, necessitating a change in the design requirements or cleaning procedures, in which case the shipper shall so notify the carrier and, as necessary, the loader in writing before the shipment.

(Comment 120) A comment observes that a shipment may change hands many times during transit as it is transferred between carriers. The comment notes that in these instances, the shipper is not in contact with all of the subsequent carriers that may be involved and, therefore, would not be in a position to ensure its original requirements are met from start to finish. Therefore, the commenter argues that the original carrier, which has initial responsibility for ensuring that the food is handled in accordance with the shipper's requirements, should be responsible for transferring that responsibility to the next carrier down the line. The comment also states that, although an overseas shipper is in the best position to know the transportation conditions appropriate for a given food shipment when it is initiated, the shipment could change hands after it arrives in the United States and the sequential carriers, therefore, should bear responsibility for ensuring that the food is handled in accordance with the shipper's requirements.

(Response 120) This rule would require that the shipper meet the requirements of § 1.908(b)(1) for all segments of a shipment's transit, no matter how many carriers might be involved in the transportation process. As we discuss in our response to Comment 70, those requirements have been established for the shipper based upon our determination that the person who arranges for the transportation of food by a carrier, *i.e.,* the shipper, is best suited to perform these functions.

(Comment 121) A comment addressing vehicle cleaning procedures states that with the exception of food-grade tanker trucks, there are no industry standards or protocols for cleaning and sanitizing vehicles that transport food. The comment opines that, other than general statements regarding the need to supply vehicles and transportation equipment that prevent food from becoming adulterated, the rule seems to allow shippers and carriers to agree upon the required cleaning practices. The comment also offers the view that the flexibility provided for by the rule may not be adequate, given the lack of any industry standards or vehicle and equipment cleaning best practices. Finally, the comment notes that if we elect to impose vehicle and equipment cleaning standards, we must recognize that there are a limited number of vehicle washout facilities available to the transportation industry, and that they vary in the type of services they are capable of providing.

(Response 121) The commenter is correct that this rule provides flexibility to shippers and carriers to determine the appropriate protocols for cleaning transportation vehicles and equipment to comply with the requirements of this rule. In general, we do not expect that the requirements of this rule will necessitate a change in the procedures for vehicle and equipment cleaning. Nonetheless, § 1.908(b)(1) will require that these procedures be communicated to the carrier in writing. However, as we stated in response to Comment 116, this provision allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of this rule. We understand that a shipper could reasonably determine that it is not necessary to specify any procedures that are commonly understood by carriers, *e.g.,* removal of dunnage, sweeping. To the extent that there is a need for guidance on cleaning procedures that go beyond those that are commonly understood, but not as extensive as those for bulk tankers (for which there is written industry best practice, as noted by the comment) we will consider issuing guidance or working with industry trade associations to develop written industry best practice on this subject.

We are not establishing vehicle cleaning standards in this rulemaking. This rule provides flexibility to shippers and carriers to determine the appropriate protocols for cleaning transportation vehicles and equipment to comply with the requirements of this rule. We will consider issuing guidance on this subject in the future should the need arise.

(Comment 122) One comment asserts that the proposed rule lacks sufficient flexibility to ensure that it can be implemented effectively by the food transportation industry. According to the comment, shippers are not always sufficiently knowledgeable to be able to specify "all necessary sanitary requirements for the carrier's vehicle and transportation equipment." The comment also observes that shippers, carriers, and receivers typically work together to establish sanitary requirements that are appropriate for each particular type of food shipment.

(Response 122) Persons responsible for complying with this rule may work with any other persons covered by this rule or third-party experts, for assistance in developing their specifications. For example, a shipper that is not the manufacturer may consult with the manufacturer or with a third-party expert.

(Comment 123) One comment states that the design and construction of tanker trucks varies across the transportation industry and that variations can occur even within a given vehicle manufacturer's model lines. According to this comment, a preparatory procedure that is suitable and adequate for one tanker, therefore, may not necessarily be suitable and adequate for a differently designed or constructed tanker, and only an individual carrier has the best knowledge of the characteristics of its particular tanker.

(Response 123) In order to prescribe the appropriate sanitary conditions for shipment of a bulk cargo, the shipper must have knowledge of the safety requirements of the food, as well as the construction of the vehicle and transportation equipment. We expect that the shipper will either have that knowledge based on prior training or experience, or will obtain information from someone with the necessary expertise. In the case of knowledge about the construction of tankers, it may well be that the shipper's best source of information will be from the carrier. An exchange of information between the carrier and the shipper, leading to a written specification from the shipper to the carrier, is fully consistent with the intent and language of § 1.908(b)(1).

(Comment 124) One comment asks us to confirm that a shipper's written communication required by proposed § 1.908(b)(1) can be executed for a particular commodity for the duration of its agreement with each carrier rather than just for each particular product load. A second comment suggests that this requirement should specify that one-time notifications will be sufficient unless the design requirements and cleaning procedures required by the shipper change because of changes in the types of food being transported, in which case the shipper would be required to supply the carrier with a new written notification.

(Response 124) We agree with both commenters. Therefore we have added the language to § 1.908(b)(1) in this final rule that states that one-time notification shall be sufficient unless a factor, *e.g.,* the food or the conditions of shipment, changes, necessitating a change in the design requirements or cleaning procedures, in which case the shipper shall so notify the carrier, and, as necessary, the loader, in writing before the shipment.

b. Proposed § 1.908(b)(2)

We proposed to require that a shipper must visually inspect the vehicle or the transportation equipment provided by a carrier for cleanliness before loading food that is not completely enclosed by a container onto a vehicle or into transportation equipment provided by the carrier. We proposed that the shipper would have to determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, for example, that it is free of visible evidence of pest infestation and of debris, of previous cargo, or of dirt that could cause the food to become adulterated (revisions to the proposed provision are discussed in Comment 89). As we previously discuss in several sections of this document, responsibility for the pre-loading inspection no longer resides with the shipper, as we had initially proposed. Rather, in this final rule, the loader now bears this responsibility under § 1.908(c)(1).

(Comment 125) One comment states that proposed § 1.908(b)(2) is inapplicable to bulk liquid tanker shipments because personnel do not enter the cavity of a tanker after it has been cleaned and made ready for loading. The comment recommends that we modify this requirement to make it goal-based by requiring the shipper to determine that the vehicle or transportation equipment is in sanitary condition for the transport of the food by any appropriate means. The comment also asks us to provide examples of ways to accomplish this, for example, through the use of visual inspection, documentation, or cleaning.

(Response 125) We agree that the preloading inspection requirement in this final rule should specify the inspection's objective without restricting it to a specific method, *e.g.*, visual inspection. We have decided that the objective of pre-loading inspections should be a determination that the vehicle or equipment is in appropriate sanitary condition for the transport of food. At times, *e.g.*, transportation of food that is not fully enclosed by a container, such an inspection would generally involve a visual inspection to ensure that the walls, floors, and ceiling of the vehicle are adequately clean, such that they are not likely to cause the food to become unsafe during transportation. However, at other times, *e.g.*, bulk shipments in tanker trailers, the tanker trailer may already be washed and sealed before it arrives at the shipper's place of business, and the inspection may be as simple as checking for a wash ticket. We therefore have revised this provision in § 1.908(c)(1) to state that the loader must determine through the pre-loading inspection process that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.*, it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. We have also revised this provision to state that this inspection may be accomplished by any appropriate means.

(Comment 126) One comment states that checking for the physical condition of a vehicle during the pre-load inspection, for example, checking for holes in the floor, walls and ceiling and the presence of off-odors and stains that might constitute residual evidence of a chemical spill or pooled water, is not specifically included in proposed § 1.908(b)(2). The comment recommends that we expand the scope of the pre-loading inspection to include these items.

(Response 126) We agree that in certain circumstances, *e.g.*, transportation of food that is not fully enclosed by a container, the items discussed in the comment should be included in a pre-loading inspection. However, we are not specifying preloading inspection requirements in this rule because the nature of these inspections may vary from one type of operation to another depending on what would be necessary to determine that the vehicle or equipment is in acceptable sanitary condition for its intended use for the transportation of food. We have added the physical condition of the vehicle as an example of what may be included in a preloading inspection in § 1.908(c)(1) of this final rule.

(Comment 127) A comment states that, during the transport of animal feed, the carrier's driver often performs loading functions without having a shipper's employee present. The comment notes that this practice is established through contract stipulations between the shipper and carrier. The shipper may also choose to inspect the truck, depending on the feed to be loaded and customer requirements. The comment further states that, as a practical matter, a bulk trailer is often inspected after delivering a load to ensure that all the feed was delivered and that it is ready for loading the next load. The commenter asserts that this practice and verification of the last load delivered, in addition to contract requirements, sufficiently ensures the safety of the feed.

(Response 127) This comment describes a situation where the carrier is also the loader. The practices described by the comment are consistent with the provisions of the final rule. In § 1.908(c), this rule requires loaders, in this case also the carrier, to take actions before loading food not completely enclosed by a container onto a vehicle or into transportation equipment to determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food. In this case, where a dedicated bulk truck is repeatedly used for the same cargo that does not require refrigeration for safety, *e.g.*, animal feed, an inspection of the inside of the bulk vehicle after delivery of a load may be sufficient to ensure that it is in a suitable condition for loading the next shipment.

(Comment 128) A few comments address proposed § 1.908(b)(2) within the context of partial load shipments, which are also known as less-than-truckload (LTL) shipments. LTL shipments are those in which additional loads are subsequently added to a partially loaded truck. These comments state that the shipper of a partial load will likely be present only for the loading of its own shipment, but not for subsequent loads, and therefore cannot "visually inspect the vehicle . . . for cleanliness" or ensure "that the vehicle . . . is in appropriate sanitary condition" for subsequent loads. One of these comments states that the rule must also account for cross-docking situations in which cargo is transferred from the original vehicle to another vehicle or mode of transport. In cross-docking transfers, employees of neither the shipper nor receiver will be present during loading into the subsequent vehicle, and the subsequent vehicle may even be from another carrier.

(Response 128) Under this final rule, the loader, and not the shipper or receiver, is responsible for performing the inspection upon loading as required by § 1.908(c)(1). This requirement would apply to the loader for each sequential loading of a vehicle that makes multiple stops to pick up partial loads. This also applies to the loader for a trans-loading (cross docking) operation, as we discuss in our response to Comment 38.

c. Proposed § 1.908(b)(3)

We proposed to require that a shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, whether a TCS food or a non-TCS food, must specify in writing to the carrier, except to a carrier who transports the food in a thermally insulated tank, the temperature conditions needed during the transportation operation, including the pre-cooling phase, to ensure that the carrier will maintain the proper temperature and meet the requirements of § 1.908(a)(3). We also proposed to make this information subject to the records requirements in § 1.912(a) of this rule.

(Comment 129) A large number of comments oppose our proposed provisions in § 1.908(b) and (d) for shippers and carriers engaged in the transportation of temperature controlled foods. These comments urge us to incorporate provisions into this rule that would allow for the continued use of existing food transportation industry best practices that have proven to be effective. They argued that management of temperature control for foods during transportation is a complex issue because it involves interactions between shippers, carriers and receivers who must address a variety of circumstances that may arise during the transportation of the food. We will first summarize the numerous comments we received on this matter.

- These comments universally oppose any requirement that carriers routinely demonstrate for each delivered load that they have met shipper temperature specifications. They state that confirming the functionality and settings of the refrigerator unit, or the temperature of the compartment upon loading and upon receipt, and visually inspecting the food upon arrival for signs of temperature abuse is sufficient. The comments note, for example, that when a truck arrives at its destination, the receiver checks the trailer temperature setting. The receiver often also conducts a visual inspection to confirm that there are no visible signs of temperature abuse, such as sweating, the presence of ice crystals, signs of moisture, leaking products, moisture damage to packaging, or the loss of the structural integrity of packaging. According to these comments, checking the temperature of the food itself after transport has not been found to be necessary for purposes of ensuring food safety. The comments state that this is the case, in part, because if a refrigeration unit is turned off during shipment long enough to affect the temperature of the food product, a visual inspection of the food would be sufficient for purposes of determining whether a material temperature deviation that would have affected the safety of the load had occurred. The comments, therefore, assert that the current standard industry practice in most cases is to request temperature information about the load from the carrier upon delivery if there is a suspected food safety problem, for example, as indicated by a visual inspection.

- These comments also note that truck trailers often have devices onboard that can continuously record the refrigeration unit temperature that can be reviewed when necessary to investigate potential temperature deviations during transport that could affect food safety. These comments state, however, that this recorded information can be difficult to download and takes considerable time and expense to analyze because the process involves, among other things, identifying the container unit in transit, removing it from service, and delivering it to a facility capable of downloading the data. The comments further state that the cost of just extracting the data can be up to $200 per load and may require the services of a third-party vendor and that additional expense is incurred in analyzing the data. The comments therefore conclude that requiring the routine review of recorded onboard refrigerator temperature data is neither practical nor necessary.

- These comments also argue that the language of proposed § 1.908(d)(2)(i) could be interpreted to require continuous temperature monitoring during food transport and suggest that we may be under the misimpression that the use of continuous monitoring devices is the norm in the refrigerated food transport industry. Some comments state that current best industry practices in many cases can give shippers confidence that appropriate temperatures are maintained during transit, without the use of continuous monitoring devices. One comment urges us to permit other forms of adequate temperature monitoring, such as documented alarm systems or properly documented manual temperature records. Many comments state that the rule should allow the carrier to use any means agreeable to the shipper to demonstrate the carrier's adherence to temperature specifications, such as recording trailer temperature settings when the vehicle is loaded and unloaded or periodic temperature checks during transit. Finally, some of the comments note that with the limited exception of the transportation of highly temperature-sensitive food products, such as vacuum packed seafood, where the shipper or receiver voluntarily may determine that the use of continuous monitoring devices is necessary to ensure product safety, using continuous temperature monitoring and recording devices is not necessary for purposes of ensuring the safety of the food during transport.

- These comments also state that a deviation from the shipper's temperature specifications does not necessarily cause the food to be unsafe. According to the comments, the temperature included in a shipment's bill of lading is the temperature at which the trailer's refrigerator unit needs to be set, but is often lower than the temperature needed to ensure the safety of the food shipment. A food that requires time/temperature control to ensure its safety (TCS food) and needs to be maintained at or below 40 degrees Fahrenheit, for example, may be transported during the winter in cold regions of the country at refrigerator settings very close to 40 degrees because this is adequate to ensure the temperature required for safety is not exceeded given the low outside air temperature. If, however, this food is transported during the summer, the shipper may direct the carrier to set the refrigerated trailer temperature much lower than 40 degrees Fahrenheit (*e.g.*, 33 degrees Fahrenheit) because the warmer outside air temperature could cause the ambient temperature in the trailer to rise during transit. In this scenario, according to these commenters, the ambient temperature in the trailer upon arrival at the receiver's facility may be 36 degrees Fahrenheit, but this does not mean that the food is unsafe, even though the temperature is higher than what was indicated in the shipment's bill of lading. These comments conclude that for these reasons, this rule should clearly state that a deviation from the shipper's temperature specifications does not necessarily cause the food to be unsafe.

- Finally, these comments urge us to accord shippers the flexibility to assess the conditions under which the food was transported in determining whether temperature deviations cause the food to be unsafe. The commenters assert that, in many cases, the food may still be fit for its original intended use, notwithstanding any temperature deviations that might have occurred during transit. The comments also assert that in a case where a food may no longer be fit for its original intended use because of temperature deviations, the food may still be fit for an alternative use. A food product that may no longer be fit for its intended use as food for humans because of temperature deviations that might have occurred during transit, for example, might still be safe and fit for use as animal food. The comments argue that automatically deeming food adulterated because there was a temperature deviation during transit, without allowing for an evaluation of whether that deviation affected the safety of the food, would result in significant amounts of food waste without providing any corresponding food safety benefit.

(Response 129) We agree that the provisions we proposed for persons engaged in the transportation of foods that require temperature control for safety should be revised to clearly focus their requirements on functions that ensure that adequate temperature control is provided, and to permit the continued use of established industry best practices that provide for the safe transportation of these foods. In revising these provisions, which are now designated as § 1.908(b)(2) in this final rule, we considered the steps that occur before, during, and after the transportation of foods that require temperature control for safety to ensure the transportation operation is in accord with sanitary transportation practices. Our changes to this final rule involve revisions that affect the responsibilities of shippers (§ 1.908(b)), loaders (§ 1.908(c)), receivers (§ 1.908(d)), and carriers (§ 1.908(e)).

In revising this rule's provisions for foods that require temperature control for safety during transportation, we recognized the fact, expressed in several comments, that the temperature control measures we are establishing in this rule may not be necessary for some transportation operations, *e.g.,* those conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances. As such, we are using in § 1.908(b)(2), the phrase, "food that requires temperature control for safety under the conditions of shipment," to indicate that the requirements of this provision do not apply in situations in which the shipper determines that they are not necessary to ensure that the food does not become unsafe during transportation. We would expect that a shipper would be able to articulate the basis for any such determination if asked why temperature control is not necessary under the conditions of shipment.

Under conditions of shipment where it is necessary to provide temperature control to ensure that food does not become unsafe during transportation, the shipper must provide written instructions to the carrier and, when necessary (*e.g.,* if the shipper is not also the loader), to the loader, specifying temperature conditions to be maintained during transport.

The comments we received clearly state that this provision, as proposed, may be interpreted to mean that we are requiring the shipper to specify a critical limit for the transport of the food, such that food held in a vehicle that exceeds the specified temperature may be unsafe and, therefore, adulterated. We recognize that under established industry practices, the temperature specification provided to a carrier is often lower than the temperature needed to ensure food safety and that if the ambient temperature in a trailer were to exceed the specified temperature, the food would not necessarily be unsafe. We agree with the comments that ask us to clarify that a deviation from the shipper's temperature specifications does not necessarily and automatically cause the food to be unsafe, and, therefore, adulterated. Therefore, we are revising this provision in § 1.908(b)(2) to require that the shipper specify to the carrier, and, when necessary, to the loader, an operating temperature required for the given transportation operation, including, if necessary, the pre-cooling phase. We are adding a definition for the term "operating temperature" in § 1.904 to state that this term means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, *e.g.,* seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of § 1.908(a)(3). This revision clarifies that we do not intend for the temperature specified by the shipper to the carrier to be used as a critical limit, and that we understand that the specified temperature might be exceeded because of foreseeable circumstances that occur during transport, and that such deviations do not necessarily cause the food to become unsafe, and, therefore, adulterated.

We next considered how this rule should address temperature monitoring during transportation and under what conditions data acquired during temperature monitoring should be communicated by a carrier to a receiver or shipper. The comments we received clearly state that under established industry practices, parties involved in food transportation use a wide variety of approaches for monitoring temperature conditions. In some instances, for example, the transportation of some vacuum packaged seafood products, the continuous monitoring of temperature during transportation is necessary to ensure that the food is maintained under safe conditions. In most other instances, the transportation industry relies primarily on means, other than reviewing temperature monitoring information acquired during transit, to establish that adequate temperature control was provided during transportation, *e.g.,* vehicle temperature checks at loading and unloading, product temperature checks at receiving. In some instances, *e.g.,* cross-country shipments, manual vehicle temperature checks may be made periodically during transit.

We agree with comments that state that the proposed rule could be interpreted to require continuous temperature monitoring during transit, due in part to the proposed requirement at § 1.908(d)(2)(i) that a carrier must, once the transportation operation is complete, demonstrate to the shipper, and if requested, to the receiver, that it maintained temperature conditions during the transportation operation as specified by the shipper. We affirm that the carrier bears the responsibility for demonstrating, when necessary, that it transported food under appropriate temperature control conditions consistent with those specified by the shipper. However, we have revised this final rule at § 1.908(e)(2) to allow that demonstration to be made by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting recordings of the ambient temperature of a trailer when it was loaded and unloaded, or in the form of time/temperature data recorded during the shipment. This revision also clarifies that we are not requiring that the carrier conduct continuous monitoring of the temperature conditions on a vehicle during transport, but it also recognizes that in some circumstances it may be necessary to ensure the safety of the food and that, in these circumstances, the shipper and carrier may agree to this approach.

We also considered circumstances in which it would be necessary for a carrier to provide information to the shipper about temperature conditions during shipment. We agree with comments that state that requiring a carrier to routinely demonstrate for each delivered load that it had met the shipper's temperature specifications is not necessary for purposes of ensuring food safety and is not consistent with current industry best practice. Therefore, we have revised this rule at § 1.908(e)(2) to provide that the carrier's demonstration must be made only upon request by the shipper or the receiver. This revision clarifies that a carrier is not required to routinely provide this demonstration, but requires such a demonstration when, for example, as explained below, the receiver assesses the food upon receipt and determines that there may have been a material failure of temperature control during the shipment, or when the shipper and receiver have agreed that it is necessary to ensure the safety of the food (*e.g.,* some shipments of vacuum packaged seafood).

We also considered what measures, if any, should be required after a food transportation operation has been completed. Many of the comments that we received observe that receivers currently routinely check the function and settings of the transportation vehicle's refrigeration unit and conduct visual inspections of the delivered food products for which temperature control is required for signs of temperature abuse. We regard these types of inspections as essential for ensuring that the food was transported in accordance with appropriate sanitary transportation practices and was not rendered unsafe because of inadequate temperature control. Accordingly, we have revised this final rule in § 1.908(d), which now includes requirements applicable to receivers, to provide that upon receipt of food that requires temperature control, a receiver must take steps to determine whether the food was subjected to significant temperature abuse. We also have provided examples of measures a receiver could employ for this purpose, such as determining the food product's temperature, the ambient temperature of the vehicle and its refrigeration unit's temperature settings and conducting a sensory inspection to ascertain whether there are signs of temperature abuse, such as off-odor. We also note that the receiver at this stage may review temperature monitoring information from an onboard temperature monitoring device that might have been employed during the food transportation process, and that such an approach would meet the requirements of this rule.

We also added a provision to the general requirements of this rule § 1.908(a)(6) that is applicable to circumstances in which temperature abuse of a food may have occurred or another event may have occurred that could have jeopardized the safety of the food (*e.g.*, spillage of a toxic substance on food items in the same load). This provision states that if a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the person must take appropriate action, to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual, that the temperature deviation or other condition did not render the food unsafe.

This provision would, for example, require a receiver of food that requires temperature control for safety, that has performed a check of the vehicle compartment temperature as a way to comply with § 1.908(d), and determined that the temperature is above the operating temperature specified by the shipper, to hold the product until it can make a determination that the temperature deviation did not make the food unsafe. It could make that determination on its own, if it is qualified to do so, or could consult with the carrier, loader, shipper, or a third party to make such a determination or to assist it in making such a determination. Whomever makes such a determination should be qualified by training or experience to make such a determination, *i.e.*, he should have a scientific understanding of how the temperature deviation could affect the growth of pathogens or production of toxins in the food. It is our expectation that, under such a circumstance, the receiver (or shipper, if that is the more appropriate party to make the determination) would request temperature control information from the carrier. The carrier would be obligated to provide that information to the shipper or receiver under the provisions of § 1.908(e)(2).

We have included in § 1.908(a)(6) a provision that, if requested by the receiver, the carrier must provide to the receiver the operating temperature specified by the shipper in accordance with § 1.908(b)(2). This is a necessary exchange of information to facilitate the receiving examination provided for in § 1.908(d), when the receiver may not be aware of the operating temperature that the shipper provided to the carrier.

The new provision at § 1.908(a)(6) would also, for example, require the carrier of a food that notices leakage of liquid from boxes of raw poultry onto partially enclosed crates of produce during a stop in transportation to hold the food until the carrier can obtain a determination from a qualified individual, *e.g.*, the shipper, that the condition did not cause the food to be unsafe for its intended use.

We agree with the comments that we received that argued that if a food has become unfit for its intended use because of material temperature abuse during transportation, the food may still be fit to an alternative use, such as for animal food. We would judge such circumstances on a case-by-case basis.

We have further modified the provisions of proposed § 1.908(b)(3) (now § 1.908(b)(2)) in several ways. First, because we have added a definition of loader, in response to comments that urged that we account for activities performed by the person loading a vehicle when that person is not also the shipper, receiver or carrier (see Comment 70), we recognize that there will be times when the shipper must provide instructions to the loader in addition to the carrier, *e.g.*, instructions about pre-cooling conditions to look for during the a preloading inspection. For this reason, we have included the loader as a person to whom the shipper must provide instructions about the sanitary specifications for the carrier's vehicle, when necessary. Second, we have changed the proposed phrase "food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, whether a TCS food or a non-TCS food" to "food that requires temperature control for safety" for consistency with our previously stated objective of focusing this final rule on food safety only.

Finally, we have prefaced the requirement with the phrase, "Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety." We have added this language in response to comments from the railroad industry (see Comment 53) that stated that they generally do not have a relationship with shippers whereby the shipper provides them with instructions relative temperature control of the railcar that they are to deliver. Our intent is that the language will establish the requirements of § 1.908(b)(1) as the default arrangement whereby the shipper ensures that the vehicle is operated during transportation at a temperature that prevents the food from becoming unsafe by providing instructions to the carrier and, when necessary, the loader, while also allowing for alternative arrangements (*e.g.*, whereby the shipper personally ensures that the temperature conditions are met), when that is consistent with the shipper's written SOPs, as provided for in § 1.908(b)(5). We expect that many shippers that work with rail carriers will elect this latter approach, relieving them of the necessity to instruct the carrier about the necessary temperature control conditions for the railcar.

(Comment 130) Several comments state that the proposed temperature control requirements are excessive and inappropriate for the animal food industry, and ask us to revise and better align them with risk-based practices that are commonly used in that industry. One comment states that refrigeration and temperature control are not relevant to rendering industry ingredients because the high-temperature cooking process of rendering destroys the pathogens contained in the raw materials. Another comment states that maintaining temperature conditions should only be considered when a firm has identified a hazard that needs to be controlled.

(Response 130) We have revised § 1.908(a)(3), as we discussed in our response to Comment 2, to clarify that the type of food involved, for example, animal feed, pet food, human food, and the food's given stage in the production process, for example, whether the food is a raw material, an ingredient, or a finished food product, must be considered when determining the conditions and controls, including temperature controls, that may be necessary to ensure the sanitary transportation of the food. We, therefore, agree that it would not be necessary to provide temperature control during the transportation of ingredients destined for rendering because these materials will eventually be treated with high heat to destroy pathogens. As we have previously stated, we have revised this final rule so that it focuses entirely on food safety issues. For this reason, control of temperature during transportation would not be required by the rule if such control is not necessary to ensure its safety, *e.g.*, where its only purpose is to minimize decomposition of the food.

(Comment 131) Two comments observe that the proposed rule does not address the issue of how a shipment of food requiring temperature control, for which a material failure of temperature control during transport is suspected, should be handled. One of these comments expresses the view that that the rule should remain silent on this matter. The other comment argues that the issue is beyond the scope of this rule and the matter would be best resolved by a risk assessment to be conducted by the receiver and/or shipper.

(Response 131) As we explained in our response to Comment 129, we have revised § 1.908(a)(6) of this final rule to require that if a person subject to this rule becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the person must take appropriate action, to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual, that the temperature deviation or other condition did not render the food unsafe.

While we agree that it is unnecessary to prescribe the details of the mechanics of how such a determination is made, we do not agree that the actions of a receiver after taking delivery of a food shipment that may have been transported without appropriate temperature control, for example, are beyond the scope of this rule. We are charged under the 2005 SFTA to establish sanitary transportation practices to be used by shippers, carriers by motor vehicle or rail vehicle, receivers and other persons engaged in the transportation of food to ensure that food is not transported under conditions that may render it adulterated.

As we discussed in our response to Comment 129, we revised § 1.908(d) to establish duties for receivers of foods that require temperature control because we have determined that they are essential for ensuring that the food was transported in accordance with appropriate sanitary transportation practices, consistent with industry best practices. The new provisions at § 1.908(a)(6) are an appropriate extension of the provisions at § 1.908(a)(6), in that they ensure that the safety of the food is verified before a suspect food is moved further in commerce.

(Comment 132) A comment asserts that if a shipper is shipping a TCS food product and holds it unrefrigerated on a dock before the food is loaded into a transportation vehicle, the temperature of the product will rise, which will increase the ambient temperature of the refrigerated trailer compartment after the food is loaded, perhaps causing a deviation from the shipper's temperature control specifications. The comment argues that this outcome is completely beyond the carrier's control and that it needs to be taken into account when monitoring the temperature of the transportation vehicle throughout the transport process.

(Response 132) Under § 1.908(a)(3)(iii), persons subject to this rule must ensure that food that requires temperature control to prevent it from becoming adulterated during transportation is transported under adequate temperature control. This requirement also applies to the holding of food on a loading dock. Responsibility for complying with this requirement resides with the loader and not with the carrier. Although this rule does not require the use of temperature controlled loading docks, it does require that the loader handle food that requires refrigeration for safety in such a way that will prevent it from becoming unsafe. This may be accomplished by a loader by, for example, rapidly moving the refrigerated product from its refrigerated storage to a precooled vehicle, or by temporarily holding the refrigerated product in a refrigerated loading dock prior to loading onto a precooled vehicle backed up to the loading dock.

(Comment 133) Several comments ask us to clarify that the written temperature condition specifications that shippers must provide to carriers can appear in existing documents, such as contracts or bills of lading, and that they do not have to be conveyed by shippers to carriers in new, separate, dedicated documents.

(Response 133) We agree. The shipper may meet the requirements of § 1.908(b)(2) by communicating written information to the carrier in the form of existing contracts or bills of lading. Shippers do not need to create new, separate written temperature conditions specification documents for transmittal to carriers.

(Comment 134) Some comments state that the proposed rule can be interpreted to require pre-cooling only when it is necessary to maintain temperature conditions during transport, and ask us to clarify this point. One comment, for example, states that pre-cooling may not be required for transportation during the winter in cold areas or for short distance transportation of food.

(Response 134) We did not intend to suggest in the proposed rule that a shipper must always provide pre-cooling parameters to a carrier for the transportation of foods subject to the temperature control requirements of this rule. We agree that pre-cooling may not be required for transportation operations conducted during winter in cold areas or for short distance transportation of food in appropriate circumstances. Under this rule, the shipper must determine whether pre-cooling a vehicle or transportation equipment by the carrier is necessary for the sanitary transportation of the food being shipped. We have revised § 1.908(b)(2) to clarify this point by specifying that the shipper must provide pre-cooling specifications to the carrier and when necessary, to the loader (*e.g.*, if the shipper is not also the loader), only if the shipper deems this step to be necessary to ensure that the transportation operation will be conducted under such conditions and controls necessary to prevent the food from becoming unsafe.

(Comment 135) One comment states that pre-cooling transportation equipment is inadequate without pre-cooling the product. The comment singles out RACs as an example, noting that if the RACs are not adequately pre-cooled prior to transportation, they will cause the temperature of the pre-cooled carrier container to rise above the specified temperature limits, thereby potentially creating conditions for bacterial growth. Another comment asks us to modify the language of this rule to clarify that it does not prevent the loading of harvested RACs directly from the field into pre-cooled trailers provided by carriers. This comment states that although under these circumstances, the temperature in the trailer will increase after is has been loaded, this is still a beneficial practice because it begins decreasing the field heat of RACs as soon as possible. The commenter asks us to allow this practice to continue even though it may not be possible for a carrier operating under these circumstances to meet the proposed requirement that the carrier follow the shipper's temperature controls.

(Response 135) Under § 1.908(a)(3) of this rule, all transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe. In addition, it is the shipper's responsibility under § 1.908(b)(2) (revised from proposed § 1.908(b)(3)) to specify to the carrier and, when necessary, the loader, whether pre-cooling a vehicle or transportation equipment is necessary for purposes of compliance with this rule. We have added the term "if necessary" to the pre-cooling provision of § 1.908(b)(2) to clarify that we are not requiring pre-cooling in all circumstances. If pre-cooling the food product is necessary to meet the requirements of this rule, we would expect that the shipper and the loader would ensure that this step is effectively applied as part of their responsibilities under this rule. As we discuss in our response to Comment 129, however, we have made it clear in this rule, as revised, that we are not requiring shippers to specify temperatures to carriers and loaders that would be regarded as critical limits for food safety purposes. Accordingly, an increase in the temperature of the food compartment of a pre-cooled vehicle after products that have not been pre-cooled have been loaded into the compartment would not necessarily be of concern, as long as the temperature control measures applied during the operation ensure that the food will not become unsafe during transportation. Finally, nothing in this rule specifically precludes the loading of harvested RACs directly from the field into pre-cooled trailers provided by carriers because most RACs are refrigerated during transportation to minimize spoilage and not to ensure their safety. Exceptions include seed sprouts and raw molluscan shellfish.

(Comment 136) Some comments ask us to acknowledge that pre-cooling procedures should account for the potential for condensation formation during loading operations. One of these comments states that a transit container should be pre-cooled only if it is connected to a cold storage unit because product temperature and container temperature need to be in equilibrium to prevent hotter air from entering the container when its doors are opened during loading. The entry of hotter air into the container causes condensation, which can create a number of problems, including the formation of ice and structural damage to shipping containers.

(Response 136) Under § 1.908(a)(3) of this rule, all transportation operations, including loading operations, must be conducted under such conditions and controls as necessary to prevent the food from becoming unsafe. It is the shipper's responsibility under § 1.908(b)(2) to specify to the carrier whether pre-cooling a vehicle or transportation equipment is necessary for purposes of complying with this rule. We would expect that, if necessary under the requirements of this rule, the shipper (who is often also the loader), and the loader (if the loader is a different entity), will follow appropriate procedures to address the formation of condensation during the loading of a pre-cooled vehicle.

(Comment 137) One comment expresses the view that the carrier needs to have unambiguous notice that it is being tendered a shipment of food that is not shelf stable and that such notices should be uniform and clearly noted in shipping documents so the carrier can make an informed decisions regarding the handling of the shipment. Another comment recommends that the carrier should be notified in writing when a shipment includes a TCS food.

(Response 137) As we have previously stated, this final rule is focused only on food safety, and we have accordingly revised language that previously referred to "foods that are not shelf stable" to "foods that require refrigeration for safety." We are using the latter term instead of the term TCS food. We agree that it is imperative that a carrier that takes responsibility for ensuring that a food that requires refrigeration for safety be informed by the shipper the operating temperature of the vehicle that is necessary to safely transport the food. Such disclosure is now required by revised § 1.908(b)(2).

(Comment 138) One comment asserts that thermally insulated tankers should be pre-cooled after a high temperature wash. The comment is concerned that the contents of the tanker would increase in temperature if a tanker is not pre-cooled. The comment suggests removing the exclusion for a carrier who transports food in a thermally insulated tank from the requirement of proposed 1.908(b)(3).

(Response 138) We decline this request. It is our understanding that it is a common industry practice to clean thermally insulated tankers right after unloading products rather than immediately before loading. The practice would allow the tankers to cool down after a hot temperature wash. Even if a product is loaded into a thermally insulated tanker that has just been cleaned with a high temperature wash, considering the small surface to volume ratio, we do not believe that the product temperature would be raised to a degree that is significant with respect to the maintenance of appropriate temperature control.

In addition, thermally insulated tankers are designed and built to limit the degree of temperature increase of a food in a given amount of time. Therefore, we are retaining the exclusion relating to food in a thermally insulated tank from the requirement of 1.908(b)(3).

d. New § 1.908(b)(3) to (5)

Many of the previously discussed comments depicted a food transportation system that is highly diverse, with shippers, receivers, loaders, and carriers developing and implementing food safety controls that are tailored to their specific circumstances. These controls take into account the nature of the food (*e.g.,* ready-to-eat vs. RACs for further processing, animal feed vs. human food), the manner of transportation (*e.g.,* motor freight vs. rail freight), the nature of the transportation vehicle (*e.g.,* owned or leased by the shipper, receiver or carrier, tanker vs. hopper vs. boxcar, refrigerated vs. unrefrigerated), the location and distance between shipper and receiver), the relationship between the shipper and the carrier (*e.g.,* simply providing a working boxcar to providing full service transportation including temperature control assurance), and the involvement of third parties (*e.g.,* brokers, contract loaders at remote sites), among other factors. Many comments urged flexibility to allow the best practices that have evolved over time for these various scenarios to continue to be implemented as long as they are effective in assuring food safety. Perhaps the starkest differences raised in the comments were between common practices in the motor freight and rail freight sectors. Notwithstanding those differences, some members of the rail freight sector informed us that they operated in a manner similar to many of those in the motor freight sector (for example, providing services such as refueling and monitoring refrigerated units and arranging for cleaning of bulk cargo cars), and vice versa. These commenters argued that assigning specific duties to specific categories of entities (*e.g.,* shippers, carriers, even within a sector) could, in many cases, have the effect of making some arrangements that have worked over time difficult or impossible.

We acknowledge this diversity and agree that the final rule should be structured to accommodate it. We also agree that the rule should be structured as much as possible so as not to restrict innovation in the relationships between the parties covered by the rule. On the other hand, we are compelled to develop a rule that is not so fluid that it is unenforceable. Especially when things go wrong, it is important to know who is responsible for what functions and to be able to hold them accountable. Even during day to day operations, it is important for the interacting parties to know where they are responsible and the responsibilities of the other parties, in order that all parties understand their roles and are sufficiently motivated to accomplish their piece of the system.

In response to Comment 70, we have explained our thinking relative to the revised definition of shipper, which reads, "a person who arranges for the transportation of food by a carrier or multiple carriers sequentially." We explained that we have concluded that this is the entity that is in the best position to determine the necessary conditions for safe transportation of food. Further, this is the party that causes the food to move in commerce, and, as a result, we believe, should bear the burden of setting out the safe conditions for that movement and assuring that they are met. As a result of these determinations, we have concluded that the shipper should be charged by this rule with developing and implementing written procedures that address how the safety of the food will be assured relative to the three major focus areas of this rule, to the extent that they apply to the foods that they ship. The three major focus areas are: (1) Assurance that vehicles and equipment used in its transportation operations are in appropriate sanitary condition; (2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and (3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control. It is necessary for these procedures to be in writing in order to facilitate consistent implementation by the shipper, especially with changes in personnel, and to provide for effective enforcement by FDA and other regulatory agencies. We expect that shippers would maintain such written procedures to facilitate their operations.

We recognize that, while the shipper is charged with developing and implementing these procedures, in many scenarios the shipper will need to secure the services of other parties, such as the receiver, loader, or carrier, to accomplish some or all of the measures. We expect that those services will be secured under a written agreement, subject to the records requirements of § 1.912(a). It is necessary for these agreements to be in writing in order to facilitate a consistent understanding of responsibilities and consistent implementation of the provisions by the shipper, carrier, loader and receiver, and to provide for effective enforcement by FDA and other regulatory agencies. Again, it is our understanding, based in part on comments discussed earlier in this document, that such agreements, usually in the form of contracts, are consistent with industry best practice.

Consequently, we have added three new sections to the proposed rule at § 1.908(b)(3) to (5). These new sections require that:

- A shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* that will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a).
- A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a).
- The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement, subject to the records requirements of § 1.912(a), and must include measures equivalent to those specified for carriers under § 1.908(e)(1) to (3).

We proposed at § 1.908(b)(5) that the shipper assumes the requirements applicable to the carrier in § 1.908(d)(2)(i) with respect to providing a demonstration to the receiver if the shipper and carrier have agreed in writing under § 1.908(d)(2)(ii) that the shipper is responsible for ensuring that the food was held under acceptable temperature conditions during transportation operations. When the shipper and carrier have established such an agreement, the shipper also assumes the corresponding records requirements of §§ 1.908(d)(6)(ii) and 1.912(b). This provision was proposed to provide flexibility in the manner in which temperature control was assured during transportation, and, in particular, who was responsible for demonstrating to the receiver that such control was maintained. This provision is no longer necessary, and has been deleted from the final rule, because the new provision at § 1.908(b)(5) provides the same kind of flexibility for temperature control assurance, for foods that require refrigeration for safety, as discussed earlier in this document.

3. Requirements Applicable to Shippers and Receivers Engaged in Transportation Operations (Proposed § 1.908(c))

We had proposed to establish requirements for shippers and receivers addressing food handling during loading and unloading, in proposed § 1.908(c). As we discuss in this section, we have determined that it is not necessary to include these requirements, as they were proposed, in this final rule. We have redesignated § 1.908(c) in this final rule to specify requirements applicable to loaders engaged in transportation operations, which we discuss in the following section.

(Comment 139) One comment states that we should ensure that receivers have the ability to test a food product before automatically discarding it because the shipper's temperature control specifications were exceeded during transport.

(Response 139) Nothing in this rule requires receivers to discard food if the food was subject to deviations from a shipper's temperature control specifications during transport. We discuss a receiver's responsibilities for handling food that requires temperature control in our response to Comment 129.

(Comment 140) Several comments oppose proposed § 1.908(c)(1) on the grounds that the provision would be unnecessarily burdensome and would not improve food safety or otherwise contribute to the sanitary transportation of food.

One comment states that foods that are shipped without being completely enclosed in packaging, such as RACs, are freely handled by consumers when offered for sale in retail establishments. The comment notes that no rule currently requires consumers to wash their hands prior to the handling these foods and that there is no evidence to suggest that transportation vehicle operators present a greater risk of contaminating food not completely enclosed in packaging than do a food retailer's employees or consumers who also handle these food products prior to consumption. The comment also argues that while our proposed rule compares § 1.908(c)(1) to requirements in the cGMP regulations for human food, particularly 21 CFR 110.10(b), they are not the same (the cGMP regulations for human food have been revised in the preventive controls for human food final rule and are now in 21 CFR part 117, subpart B). The commenter notes that 21 CFR 110.10(b) generally requires all persons who work in direct contact with food to conform to hygienic practices to the extent necessary to protect against food contamination. According to the comment, the proposed hand washing provision in this rule does not contemplate that the requirement might not be necessary to protect against contamination given the existing cGMP hygienic practices provisions.

Other comments argue that proposed § 1.908(c)(1) should only apply if the vehicle operator is reasonably expected to come in physical contact with the food. One comment asserts that this proposed requirement lacks supporting scientific data, is unnecessary, is not feasible in many instances, and would appear to be appropriate only if human contact with the food poses a risk that the food will become adulterated or otherwise poses a valid health risk to humans or animals. Another comment recommends that any requirement for hand-washing facilities be risk-based and be linked directly to the effectiveness of hand-washing for purposes of reducing the risk that human handling of food would cause the food to be rendered injurious to health or otherwise adulterated.

Another comment suggests that firms should train drivers with respect to safe handling practices and that we should leave the selection of the sanitary methods for the handling of foods not entirely enclosed by packaging up to the transportation firms. The comment suggests, for example, that vehicle operators may be instructed to use disposable gloves, sanitary wipes, and/or a customer's hand washing facilities depending on the circumstances. One comment expresses concern that this provision would require the installation of additional sinks in virtually all food distribution centers at a great cost to the industry.

(Response 140) After considering these comments, we have decided to remove the provision in proposed § 1.908(c)(1) from this final rule. We have determined that this provision is unnecessary because the specific circumstance that proposed § 1.908(c)(1) would address, vehicle operators handling food not completely enclosed by a container, is already addressed by the broader requirement of § 1.908(a)(3), which requires that all transportation operations be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations. In particular, § 1.908(a)(3)(ii) includes hand washing as an example of measures that can be taken to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. Providing vehicle operators access to hand washing facilities is one method for preventing the contamination of food, but we agree that it may not always be necessary. By removing proposed § 1.908(c)(1) from this rule, we are allowing flexibility for the transportation industry to determine what control measures would be necessary in any given set of circumstances.

Furthermore, we have reached the same conclusion concerning the provision in proposed § 1.908(c)(2), which would have required shippers and receivers of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control during transportation, to carry out loading and unloading operations under conditions that would "prevent the food from supporting such microbial growth." We have removed that provision from this final rule because our expectations for temperature control during loading and unloading operations are set forth in new § 1.908(a)(3)(iii), which requires persons subject to this rule to take effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control; see Comment 132 and Comment 141.

(Comment 141) One comment states that there are no provisions in the rule to ensure that insanitary conditions have not contaminated the food before a carrier becomes involved. The comment asserts that the rule does not require specifications for conditions that must be maintained on loading and unloading docks, and that carriers are not given an opportunity to inspect and confirm either the condition of the cargo or the facilities where the food is picked-up or delivered.

(Response 141) We disagree with the comment. The requirements of § 1.908(a)(3) and (c), while general in nature, address sanitary transportation practices applicable to the loading and unloading of food. In addition, this rule does not preclude a carrier from establishing agreements with the owner or operator of the facility or loading dock to inspect or confirm the condition of cargo or facilities prior to accepting a load.

4. Requirements Applicable to Loaders Engaged in Transportation Operations (New § 1.908(c))

As we stated in the previous section, we have redesignated § 1.908(c) in this final rule as, "Requirements applicable to loaders engaged in transportation operations." The provisions we have included in this section arise from our consideration of comments relevant to loading operations in other sections of this final rule; see Comment 125, Comment 126, Comment 127, Comment 128, and Comment 129.

5. Requirements Applicable to Receivers Engaged in Transportation Operations (New § 1.908(d))

We have established requirements applicable to receivers engaged in transportation operations in § 1.908(d) of this final rule and have moved the corresponding requirements applicable to carriers (proposed § 1.908(d)) to new § 1.908(e), discussed in the following section. The provisions we have included in new § 1.908(d) arise from our consideration of comments relevant to food that requires temperature control for safety, which we discuss in Comment 129.

6. Requirements Applicable to Carriers Engaged in Transportation Operations (Proposed § 1.908(d), Now New § 1.908(e))

As discussed in section IV.E.2, we have concluded that the shipper should be charged by this rule with developing and implementing written procedures that address how the safety of the food will be assured relative to the three major focus areas of this rule, to the extent that they apply to the foods that they ship. The three major focus areas are: (1) Assurance that vehicles and equipment used in its transportation operations are in appropriate sanitary condition; (2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and (3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control. We recognize that, while the shipper is charged with developing and implementing these procedures, in many scenarios the shipper will need to secure the services of other parties, such as carrier, to accomplish some or all of the measures. We expect that those services will be secured under a written agreement, subject to the records requirements of § 1.912. It is our understanding, based in part on comments discussed earlier in this document, that such agreements, usually in the form of contracts, are consistent with industry best practice.

Consequently, we have added three new sections to the proposed rule at § 1.908(b)(3) to (5). These new sections require that:

- A shipper must develop and implement written procedures subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.*, that will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a).
- A shipper of food transported in bulk, must develop and implement written procedures subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a).
- The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this rule under a written agreement subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under § 1.908(e)(1) to (3).

Consistent with these new provisions in the previous section applicable to requirements for shippers, we have included language at § 1.908(e) (proposed § 1.908(d)) that makes the provisions of that section applicable to a carrier only when the carrier and shipper have a written agreement that the carrier is responsible, in whole or part, for sanitary conditions during the transportation operation. Each provision is applicable only when it is relevant to the provisions of the agreement between the carrier and the shipper. For example, the carrier and the shipper may have a written agreement that states that the carrier is to precool the vehicle and set and monitor operating temperatures in the vehicle, based on instructions from the shipper. In this case, the carrier would be responsible for meeting the requirements of § 1.908(e) that are relevant to temperature control (*i.e.*, § 1.908(e)(2) and (3), discussed in this document). If the agreement did not assign responsibility for other sanitary conditions to the carrier, *e.g.*, cleanliness of the vehicle, previous cargo control, the other provisions of § 1.908(e) would not be applicable to the carrier.

a. Proposed § 1.908(d)(1)

We proposed to require that a carrier must supply a vehicle and transportation equipment that meets any requirements specified by the shipper in accordance with § 1.908(b)(1), and is otherwise appropriate to prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health from any source during the transportation operation.

We have made the following revision to proposed § 1.908(d)(1) (now § 1.908(e)(1)) for consistency with changes elsewhere in the final rule to focus the rule on food safety only. We have changed the proposed phrase "prevent the food from becoming filthy, putrid, decomposed or otherwise unfit for food, or being rendered injurious to health" to "prevent the food from becoming unsafe."

(Comment 142) One comment asks us to require LTL carriers to implement written procedures to ensure the compatibility of each food contained within an LTL load and to require that the carrier be able to demonstrate full compliance with each shipper's food transportation specifications upon request.

(Response 142) We decline to make this change. We have assigned responsibility for ensuring that a vehicle onto which food not completely enclosed by a container is loaded is in appropriate sanitary condition, to the loader, giving consideration to specifications provided by the shipper (see Comment 70). Among other factors, the loader is to consider whether the vehicle is in adequate physical condition and whether it is free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe. In the case of an LTL load, we would expect that the loader would check to see if any previously loaded cargo could potentially contaminate food not completely enclosed by a container in a subsequent load. We would also expect that the shipper of food not completely enclosed by a container on an LTL load would generally instruct the loader to inspect (where the loader and the shipper are not the same person), consistent with the shipper's obligations under § 1.908(b)(3).

(Comment 143) Another comment notes that the carrier has the responsibility for providing a container in good mechanical condition and that is reasonably clean of dirt, debris and foul odors. However, the comment states that the shipper should be responsible for any "sanitizing" that might be required for the sanitary transportation of a particular food/beverage or commodity.

(Response 143) We are aware that, depending upon the circumstances and the agreement between the parties, current practice is that either shippers, loaders or carriers may wash and/or sanitize vehicles before they are loaded, or they may contract with a third party to perform that function. We see no public health benefit in changing current practice by mandating that one party or another perform the function. As previously discussed, in new § 1.908(b)(3) we have required that shippers develop and implement written procedures specifying how they will ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. We would expect such procedures to include cleaning and sanitizing procedures as appropriate to the food and conditions of shipment. However, new § 1.908(b)(3) also provides that the shipper may reach an agreement with the carrier, or another party covered by this rule, to perform this function. If a carrier agrees to perform this function, § 1.908(e)(1) requires that they ensure that the vehicle meets the shippers specifications in that regard.

(Comment 144) One comment states that some jurisdictions prohibit carriers from washing out their truck's trailers because of local water quality regulations designed to protect the environment from contaminated water runoff. The comment further asserts that this rule, therefore, places carriers in the untenable position of having to choose which regulation to follow. The comment asks us to provide clarity regarding the interaction between this rule and state and local regulations that may restrict or prohibit truck washing.

(Response 144) This rule is not intended to preempt state and local requirements regarding water runoff and water quality issues that would affect truck washing. Carriers affected by local requirements that restrict or prohibit truck washing must, even now, determine how to meet any requirements imposed upon them by their shipper customers when faced with local washing restrictions. This rule does not change that fact. As discussed in response to the previous comment, in new § 1.908(b)(3) we have required that shippers develop and implement written procedures specifying how they will ensure that vehicles and equipment used in their transportation operations are in appropriate sanitary condition for the transportation of the food. We would expect such procedures to include cleaning and sanitizing procedures as appropriate to the food and conditions of shipment. However, new § 1.908(b)(3) also provides that the shipper may reach an agreement with the carrier, or another party covered by this rule, to perform this function. If a carrier agrees to perform this function § 1.908(e)(1) requires that they ensure that the vehicle meets the shippers specifications in that regard. In some cases the shipper may choose to perform the function, if it has facilities to do so.

b. Proposed 1.908(d)(2)

We proposed to require that a carrier must, once the transportation operation is complete, demonstrate to the shipper and if requested, to the receiver, that it has maintained temperature conditions during the transportation operation consistent with those specified by the shipper in accordance with § 1.908(b)(3). We proposed that these demonstrations may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting printouts of a time/temperature recording device or a log of temperature measurements taken at various times during the shipment. We also proposed that a carrier would not be subject to the requirement of § 1.908(d)(2)(i) if the carrier and shipper agree in writing, before initiation of the transportation operations, that the shipper would be responsible for monitoring the temperature conditions during the transportation operation or otherwise ensuring that the food was held under acceptable temperature conditions during the transportation operation. Finally, we proposed that a carrier must provide the written agreement to the receiver, if requested, and that this written agreement would be subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(5), we have removed the provisions of proposed § 1.908(d)(2)(ii), concerning alternative arrangements for the responsibility to provide temperature control information to the shipper and receiver. This provision is no longer needed because new § 1.908(b)(5) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(2)(ii).

(Comment 145) One comment asserts that an LTL carrier should have the flexibility to deviate from the temperature specified by the shipper when transporting mixed loads that contain food from more than one shipper. The comment further asserts that we should allow LTL carriers to set temperatures for such mixed loads based on the lowest temperature needed to safely transport TCS foods in any given load, even though this temperature may differ from that specified by any of the other LTL shippers.

(Response 145) We agree with the comment. Our expectation is that, generally, each of the shippers of food that require temperature control for safety in an LTL load would provide an operating temperature to the carrier. These temperatures represent temperatures that will ensure that the food does not become unsafe during transportation. In most cases, they will also assure marketability and quality preservation, as desired by the shipper. With regards to the requirements of this regulation, if a carrier who has accepted responsibility for temperature control during transit selects the coldest temperature of those provided by the shippers they will be meeting their responsibility under § 1.908(e)(2). However, we note that there may be times when a shipper does not want their product to be exposed to excessively cold temperatures for quality reasons. In this case, the shipper would be well advised to so instruct the carrier. We would consider such instructions to be outside the scope of this regulation as they do not impact food safety.

(Comment 146) Another comment asks us to develop and require carriers to adhere to air and product temperature-monitoring standards to meet the requirements specified by the shipper under proposed § 1.908(b)(3). The comment asserts that these requirements should include adequate and sanitary representative sampling methods, address appropriate temperature measurement device placement, and consider the effects of load configurations and other contributing factors on temperature control during transportation. The comment asks us to consider the potential need for shippers to require both air and product temperature monitoring and recommends that any requirements related to verification of product temperatures should be incorporated in a manner that would not involve undue or burdensome costs.

(Response 146) We do not agree. We think these types of detailed provisions are better for guidance than for regulations. Because of the diversity of transportation operations, including the variety of foods transported, we have concluded that shippers need to be given considerable latitude to develop temperature controls for their operations, as long as they do, in fact, serve to prevent the food from becoming unsafe during transportation. Some of the recommendations contained in the comment, *e.g.*, a requirement to monitor both air and product temperature, would, in many cases, establish a level of temperature control substantially more rigorous than current best industry practices, which have proven to be effective in providing for sanitary food transportation and which we have incorporated into this final rule.

c. Proposed § 1.908(d)(3)

We proposed to require that, before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control, a carrier must precool each mechanically refrigerated freezer and cold storage compartment as specified by the shipper in accordance with paragraph (b)(3) of this section.

We have made the following revisions to proposed § 1.908(d)(3) (now § 1.908(e)(3)) for consistency with changes elsewhere in the final rule to focus the rule on food safety only. We have changed the proposed phrase "food that can support the rapid growth of undesirable microorganisms in the absence of temperature control" to "food that requires temperature control for safety." We have also removed the word "freezer," because we believe that the pre-cooling of freezer vehicles is a step taken to preserve product quality and marketability and not to prevent the food from becoming unsafe.

d. Proposed § 1.908(d)(4)

We proposed to require that a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the three previous cargoes transported in the vehicle. We proposed that the shipper and carrier would be able to agree in writing that the carrier would provide information identifying fewer than three previous cargoes, or that the carrier would not need to provide any such information if procedures have been established that would ensure that the bulk vehicle being offered would be adequate for the intended transportation operation, for example, if the carrier by contract would agree to offer vehicles dedicated exclusively to transporting a single type of product. We also proposed that the written agreement would be subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(4), we have removed the provisions of proposed § 1.908(d)(4), concerning alternative arrangements for the responsibility to provide previous cleaning information to the shipper. This provision is no longer needed because new § 1.908(b)(4) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(4).

(Comment 147) A few comments support this proposed provision. One comment notes that the proposed requirement is an existing common industry practice. Another comment informs us that our proposal is feasible. Another comment expressed the view that requiring identification of the three previous loads hauled is excessive and unnecessary for accomplishing the goal of sanitary food transport.

Several comments state that it is currently common for carriers to provide information about the single previous cargo hauled on a bulk transport vehicle to shippers under procedures already in place and widely accepted within both the human and animal food transportation industries. One of these comments states that for shippers, knowing the immediately previous load hauled in a bulk conveyance and knowing whether appropriate clean-out procedures have been followed, if needed to ensure the conveyance meets the needs of the shipper based upon the type of food to be loaded, is critically important. Another comment states that knowing what type of feed was hauled in a dedicated truck immediately before the present load is useful information when assessing the possibility of the contamination of the present load. Another comment offers the view that the shipper, in accordance with the FSMA preventive controls rules, would maintain written procedures as part of its food safety plan to ensure adequate cleanout of vehicles is performed and documented. According to this commenter, this written plan should suffice in lieu of any additional documentation required to support compliance to this rule.

Another comment states that the request for three previous cargoes is impractical for LTL shipments, where tractors hauling trailers with packaged goods may stop at multiple locations to pick up shipments. Several comments assert that the carrier's release of information regarding multiple previous loads could result in the improper disclosure of sensitive business information because it could involve divulging to a shipper's competitors detailed information regarding the shipper's deliveries to their customers. A related comment asserts that the tracking of three previous cargoes is impractical, and perhaps impossible, because trailers are attached to tractor transportation vehicles on a continually changing basis.

(Response 147) These comments indicate that under current industry practices, in some cases, shippers acquire information from carriers about cargo previously transported in a bulk vehicle and that this information has value to them in ensuring that their cargo will not be at risk of contamination during transportation. In other cases, shippers do not seek to obtain this information and instead rely on other measures to ensure that contamination will not occur, such as guarantees that the carrier will provide a vehicle dedicated to transporting a single type of cargo. Further, we have concluded that such a common practice demonstrates that this provision would not adversely impact businesses because of concerns about the disclosure of sensitive business information.

However, none of the comments supported the need to identify more than the single previous shipment and some suggest that it would be unduly burdensome. We are persuaded by these comments, and, consequently, while we have retained proposed § 1.908(d)(4) (new § 1.908(e)(4)), we have revised it to require the carrier to provide, on request from the shipper (when such function is the subject of a written agreement between the shipper and the carrier as provided for under § 1.908(b)(4)), information about the last previous cargo transported in a bulk vehicle. With respect to LTL shipments, we note that this provision does not apply in circumstances where the vehicle is used to transport packaged goods. This provision only applies to vehicles in which food is shipped in bulk, with the food coming into direct contact with the inner surfaces of the vehicle.

(Comment 148) A comment asks us to exempt vehicles that transport raw materials to rendering operations from the requirement of identifying prior cargoes.

(Response 148) While we recognize that materials destined for rendering will receive a heat treatment to destroy pathogens, we are not exempting carriers from the requirement that they identify the vehicle's previous cargo to the shipper supplying raw materials to a rendering operation because the shipper might wish to determine whether the bulk vehicles carried some previous cargoes that could contaminate the raw material in a way that would not be addressed by the heat processes of the rendering operation (*e.g.,* heat stable chemical contaminants). We are retaining this provision to allow the shipper to obtain this information from the carrier, if the shipper deems it necessary for the purposes of ensuring that his product does not become unsafe during transportation.

(Comment 149) Another comment asserts that carriers that offer bulk food vehicles for food transportation already comply with comparable requirements under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and further asserts that compliance with these existing requirements is sufficient to protect food safety during transportation operations.

(Response 149) We disagree. We have not established requirements in any other regulations that carriers must provide information to shippers that identifies previous cargoes transported in bulk vehicles or that describes the most recent cleaning of the vehicle. We are establishing these requirements in this rule pursuant to the objective of this rulemaking, which is to require that persons engaged in the transportation of food use sanitary transportation practices to ensure that food does not become unsafe during transportation. The regulations we have established under the Bioterrorism Act, as they pertain to food transportation, address a different purpose. Those regulations in 21 CFR part 1 address records that must be kept by certain persons, including food transporters, that would be available to FDA to identify the immediate previous sources, and immediate subsequent recipients, of food, in order for FDA to address contamination that presents serious adverse health consequences or death to humans or animals.

(Comment 150) A comment states that if a bulk trailer is offered for loading with a wash ticket, there is little reason to provide information about what was previously hauled therein. This commenter asserts that in many cases a tractor operator will obtain a trailer with a wash ticket and not know the last food hauled in the trainer.

(Response 150) As we discuss in our response to Comment 149, we revised this rule in § 1.908(e)(4) so that carriers will only have to provide shippers with information about the previous load if the shipper requests the information (in cases where the carrier and shipper have a written agreement requiring the shipper to provide such information). We would not expect that a shipper would request this information under circumstances in which the shipper does not regard it as necessary under the terms of its business relationship with the carrier, for example, when the carrier by contract has agreed to only provide vehicles that have previously hauled compatible ingredients or to present a wash ticket to the shipper when the vehicle is offered.

(Comment 151) Another comment notes that railroads do not maintain information on previous cargoes. The commenter states that there is no industry process to track and identify prior shipments in rail cars that travel throughout the general system of rail transportation in interchange service. Railroads would not have this information for privately owned rail cars and they would not necessarily have the information for their own rail cars that have been in service on other railroads or rail cars that have been placed into pool arrangements. Finally, the commenter asks us to revise this final rule so that a railroad carrier would only be required to provide information to the shipper that identifies the three previous movements when a shipper requests this information, the railroad carrier has access to the information through its ordinary course of business, and the information is not otherwise available to the shipper.

Similar comments state that it can be difficult to obtain last-load hauled information from rail carriers unless the railcars being utilized are owned, leased, or controlled by the shipper, or the shipper is the one who is the consignee/consignor or payer of the freight bill. Currently, no consistent or reliable mechanism exists among rail carriers from which to obtain such information.

One comment states that, given the complexity of the rail transport network and the efficiency and safety of current industry practices, the final rule should exclude rail carriers to avoid imposing needless and onerous burden on railroads. The commenter states that the shipper is uniquely positioned to understand the sanitary needs of the goods it ships and therefore can prevent cross-contamination and inspect and clean railcars prior to loads.

Another comment states that section 11904 of the Interstate Commerce Commission Termination Act (ICCTA) prohibits railroads subject to the Surface Transportation Board (STB's) jurisdiction from disclosing any "information about the nature, kind, quantity, destination, consignee, or routing of property tendered or delivered to that rail carrier for transportation . . . that may be used to the detriment of the shipper or consignee or may disclose improperly, to a competitor, the business transactions of the shipper or consignee." 49 U.S.C. 11904(a)–(b). The commenter also notes that the statute prohibits other shippers from soliciting or knowingly receiving such information from a railroad. The commenter notes, for example, if loaded railcars are delivered to one shipper in a terminal area and the empty railcars are provided to a second shipper in the same terminal area, disclosing the prior load would inform the second shipper as to the nature of its competitor's previous cargo. The commenter argues that this type of disclosure is prohibited by ICCTA.

(Response 151) We acknowledge that the use of railcars in interchange service as described by these comments would likely make it difficult or impossible for the railcar's provider, *e.g.,* a railroad operator, to be able to provide information about the identity of a bulk vehicle's previous cargoes to the shipper as we proposed in § 1.908(d)(4). We also acknowledge the challenge that section 11904 of the ICCTA may pose with respect to exchanging such information for rail shipments. However, as discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* providing information about the last previous cargo of the vehicle, providing a dedicated vehicle). In the case of a rail operator that does not provide services related to the safety of bulk food cargoes to be loaded onto rail cars that they provide to the shipper (*e.g.,* identifying previous cargos) we would not expect that there would be a written agreement between the shipper and the carrier to provide such information. Consequently, this rule would place no burden upon such a rail operator to provide such information.

(Comment 152) Another comment notes that contract transportation haulers notify renderers and feed manufacturers about prior loads, including nonfoods and animal feed ingredients such as restricted use proteins (*i.e.,* relative to the concern for the agent that causes transmissible spongiform encephalopathy). The comment asserts that carriers should be responsible for cleaning out the truck trailer, container, or railcar after hauling restricted use proteins or hazardous materials before hauling other animal feed ingredients.

(Response 152) While the procedures described by the commenter may reflect the practices of most contract haulers handling raw materials for rendering, as we discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* cleaning the vehicle, providing a dedicated vehicle). We believe that it would be unnecessarily restrictive to place the burden for on food sanitation step, *i.e.,* cleaning, on a specific category of persons covered by this rule, and that the system described at § 1.908(b)(4) and (e) is sufficiently protective of public health.

This rule does not address controls for specific food safety hazards, such as the agent that causes transmissible spongiform encephalopathy. As we stated in the proposed rule (79 FR 7006 at 7011), we have established requirements in § 589.2000 ("Animal proteins prohibited in ruminant feed") and § 589.2001 ("Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy") addressing cleanout requirements and dedicated equipment requirements for equipment used in the distribution of specified feed ingredients to prevent the contamination of ruminant feed and animal food or feed, respectively.

e. Proposed § 1.908(d)(5)

We proposed to require that a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle, except that a shipper and carrier may agree in writing that the carrier need not provide any such information, if the carrier follows procedures that would ensure that the bulk vehicle offered will be adequate for the intended transportation operation, *e.g.,* if the carrier has contractually agreed to use a specified cleaning procedure at specified intervals or if the shipper cleans the vehicle at his own facility, subject to the records requirements of § 1.912(b).

Consistent with our discussion concerning the duties of the shipper as a result of the requirements of § 1.908(b)(4), we have removed the provisions of proposed § 1.908(d)(5), concerning alternative arrangements for the responsibility to provide previous cleaning information to the shipper. This provision is no longer needed because new § 1.908(b)(4) and the new language at new § 1.908(e) provide the same flexibility to assign responsibility for this function as was provided by proposed § 1.908(d)(5).

(Comment 153) Some comments support the proposed provision. One comment states that all cleanout procedures, including wash out for trailers, should be documented.

(Response 153) We have retained these provisions in this final rule with some modifications as noted in the paragraphs immediately preceding this comment.

(Comment 154) One comment asserts that given the strict procedures currently in place to manage medicated feed transport, we do not need to include a previous vehicle cleaning provision in this rule with respect to the transportation of medicated feed.

(Response 154) Under this rule as we have revised it, the shipper has the prerogative to request from the carrier information describing the bulk vehicle's most recent cleaning when a contract between the shipper and receiver provides for such information exchange. We are retaining this provision to allow the shipper to obtain this information from the carrier if the shipper deems it necessary under these circumstances for the purposes of ensuring that his product does not become unsafe during transportation. Our regulations addressing medicated feed cleanout procedures (21 CFR 225.65 and 225.165) do not provide shippers with access to this type of information from carriers. If, however, a shipper has determined that the provisions of 21 CFR 225.65 or 225.165 adequately address his circumstances, the shipper may choose to not request this information from the carrier.

(Comment 155) Another comment states that providing information to the shipper describing the cleaning of a bulk rail car is beyond the current capabilities of railroad operators. The commenter observes that railroads do not generally clean rail cars and do not track the cleaning of railcars. The commenter states that railroad operators do not have access to cleaning records for rail cars that they do not own that are cleaned by customers on site or at third-party locations. The commenter also states that, even if a railroad owns the railcar, railcar operators routinely enter into contractual arrangements whereby the lessee becomes responsible for cleaning the railcar, and that based on the lack of incidents involving food transported in bulk railcars, there is no reason to impose these burdensome requirements on railroad carriers. The commenter therefore asks us to revise this final rule to require a railroad carrier to provide information to the shipper that describes the most recent cleaning of a bulk vehicle when a shipper requests such information, the railroad carrier has access to the information through its ordinary course of business, and the information is not otherwise available to the shipper.

(Response 155) We acknowledge that the use of railcars in interchange service as described by this these comments would likely make it difficult or impossible for the railcar's provider, *e.g.,* a railroad operator, to be able to provide information about the previous cleaning of a bulk car to the shipper as we proposed in § 1.908(d)(5). However, as we discussed previously, we have revised this rule at § 1.908(b)(4) to require the shipper to develop written procedures adequate to ensure that a previous cargo does not make the food unsafe. These procedures may describe actions that the shipper may take to provide this assurance (*e.g.,* cleaning the vehicle, using a dedicated vehicle), or they can include actions that the carrier in accordance with § 1.908(e), or another party covered by this regulation may take to provide this assurance (*e.g.,* cleaning the vehicle, providing a dedicated vehicle). In the case of a rail operator that does not provide services related to the safety of bulk food cargos to be loaded onto rail cars that they provide to the shipper (*e.g.,* providing information related to the cleaning of vehicles) we would not expect that there would be a written agreement between the shipper and the carrier to provide such information. Consequently, this rule would place no burden upon such a rail operator to provide such information.

(Comment 156) Another comment asks us to permit companies to use a written single generic guideline for all hired carriers with procedures addressing prior loads and the cleaning of bulk vehicles. The comment states that if a carrier commits to a shipper to use dedicated bulk containers or compatible raw ingredients and products, there should be no need for further procedures unless the shipper and carrier want to specify further details.

(Response 156) A shipper may operate in the manner described in this comment consistent with the requirements of this rule in § 1.908(e)(4) and (5). We acknowledge that an agreement provided to all hired carriers might state circumstances in which the shipper would want to know the identity of the previous cargo and information about the most recent cleaning of a bulk vehicle.

F. What training requirements apply to carriers engaged in transportation operations? (§ 1.910)

We proposed to require that carriers must provide training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems and the responsibilities of the carrier under this rule. The training must be provided upon hiring and as needed thereafter. We also proposed to require that carriers must establish and maintain records documenting the aforementioned training. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c). In table 9, we describe revisions to proposed § 1.910 and following the table we respond to comments related to these provisions.

TABLE 9—§ 1.910 WHAT TRAINING REQUIREMENTS APPLY TO CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.910(a)	Requires carriers to provide awareness training to personnel engaged in transportation operations.	Requires carriers to provide awareness training to personnel engaged in transportation operations when the carrier and shipper have agreed via written contract that the carrier is responsible for the sanitary conditions during transportation operations.
1.910(b)	Requires that carriers maintain records documenting the training required in (a).	No change.

(Comment 157) Several comments state that the training requirements should also apply to shippers and receivers who conduct loading and unloading operations in which they contact or handle food.

(Response 157) We do not agree and affirm our tentative conclusion in the proposed rule (79 FR 7006 at 7027) that training needs for shippers and receivers would be most appropriately addressed through the training provisions in our cGMP regulations for human and animal food because these regulations contain provisions related to sanitation focused employee training specifically tailored for entities that would operate as shippers, receivers and loaders under this rule.

(Comment 158) Some comments from the railroad industry state that railroads that do not handle food should not be subject to the training requirements of this rule and that these requirements should instead apply to shippers and receivers who actually contact and handle food shipped by rail.

(Response 158) We have addressed the portion of this comment that relates to training for shippers and receivers in our response to Comment 157. We agree that carriers, including railroads, that do not perform food transportation activities that may affect the sanitary condition of food would not benefit from training related to sanitary food transportation. For this reason, we have modified the carrier training requirement to require such training when the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or part, for the sanitary conditions during transportation operations. This revision is designed to be consistent with revisions at § 1.908(b)(3), (4), (5), and (e), discussed in the relevant sections of this document, that address when the carrier is made responsible for certain sanitary conditions during food transportation operations under this rule.

(Comment 159) Some comments state that training should be available to State and local regulatory officials.

(Response 159) As we discuss in our response to Comment 19, we are aware of the training needs for regulators and we will seek to establish partnerships with other Federal Agencies, and States and Tribes in implementing this rule which would include addressing these training needs.

(Comment 160) A comment requests more information about what type and amount of training would be sufficient to meet the requirements of this rule. It also states that a one-size-fits-all approach would likely overburden carriers who have little or no contact with food in their operations and likewise be insufficient for carriers whose operations involve a high degree of contact with food. Some comments mention that the content, frequency and length of training should be within the discretion of the carrier. Some comments state that a half-day long training seems unnecessary for this regulation. One comment requests that we provide flexibility in the training requirements for the transportation of chemical food additives and GRAS substances.

(Response 160) Beyond the general requirements stated in § 1.910, we are not prescribing details on aspects of the training such as its frequency, length, and subject matter. Given the diversity of food transportation operations, we do not intend to require that the entire industry use a single training approach. Training may vary in particular aspects, *e.g.*, length, provided that it meets the requirements of this rule. Thus, firms conducting differing types of transportation operations may employ training that is tailored to their operations provided that it meets the requirements of this rule. A firm that does not transport temperature controlled foods need not train their employees and food handlers in practices for providing temperature control during transportation. Transporters of chemical food additives may exercise the same selectivity in designing training programs for their operations.

(Comment 161) Some comments ask that we acknowledge in the final rule that industry training on food and feed safety systems will be acceptable and that we will not require that training be specific to this rule.

(Response 161) If industry training programs not specifically designed to address the requirements of this rule, nonetheless meets the requirements of § 1.910, such training would be acceptable under this rule. However, note that § 1.910 prescribes that the training, among other things, address the responsibilities of the carrier under this rule.

(Comment 162) A comment states that there will not be sufficient time or resources to train "qualified individuals" during the one year implementation period following the publication of the final rule. Some comments request that we establish guidelines for the development of standardized training materials. A comment requests that we develop standardized training programs that can be downloaded from our Web site, similar to the educational materials we have made available for food defense training and education.

(Response 162) The term "qualified individual" was not used in the proposed rule. It is used in this final rule in connection with determinations that food is safe when an indication of a possible material failure of temperature control or other conditions that may render the food unsafe occurs during transportation (§ 1.906(a)(6)). While the Preventive Controls rules for human and animal feed set minimum training requirements for qualified individuals, as that term is used in those regulations, no training or other standards are set in this regulation with regard to qualified individuals.

With regard to training for carriers, small businesses will have 2 years after the publication of the final rule to comply with its requirements. All other businesses subject to this rule will have 1 year. We believe firms will be able to comply with the training requirements of this rule within their allotted timeframes given these size based compliance dates and given the relatively brief and readily accessible nature of the training we envision. We have given additional consideration to the nature of training needed to raise awareness by carriers of food sanitation concerns and controls and have concluded that it can be accomplished in less than one hour. That is not to say that some carriers may not find it valuable to provide more detailed training to individuals, for example on specific duties, such as bulk container cleaning. But the training that is mandated as a minimum by § 1.910(a) is intended to raise awareness rather than set out carrier-specific duties. It is our intention to develop and place on our Web site a course that can be downloaded or taken online that would meet the requirements of this provision. The model for this training effort is our on-line food defense training materials. We anticipate working with interested third-party alliances in the development of this material. Carriers would also be able to print a copy of a certificate of participation in the course to satisfy the training recordkeeping requirement of the rule (§ 1.910(b)). Participation in the course posted on FDA's Web site would not be mandatory. Training from other sources, or conducted in-house by carriers, may also meet the requirements of 1.910(a). Our intent is to provide a low cost (labor cost only) means of satisfying the requirement.

(Comment 163) A comment asks whether we have considered having this training be a requirement to obtain a truck driver's license.

(Response 163) A Commercial Driver's Licenses (CDL) is required to operate a tractor-trailer for commercial use. CDLs are issued by the States and are subject to requirements of DOT's Federal Motor Carrier Safety Administration. FDA has no authority to establish requirements for obtaining a CDL. Further, we believe that a requirement for safe food transportation training for all CDL holders would be unnecessarily burdensome, since many such drivers are not involved in transporting food.

(Comment 164) Some comments express willingness to work with us and other carrier and shipper organizations to develop sanitary food transportation training. Several comments state that the Seafood HACCP Alliance could best serve this purpose since it already has an established history in providing training, and has sufficient stakeholder involvement and the infrastructure in place to design, develop, and deliver training.

(Response 164) We commend the willingness of organizations to partner in developing sanitary food transportation training. Training alliances such as the Seafood HACCP Alliance have effectively functioned for this purpose in the past. We believe that a similarly constituted alliance would be useful for developing and promoting training for sanitary food transportation.

G. What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations? (§ 1.912)

We proposed that shippers and carriers: (1) Must retain all records required under this rule for a period of 12 months beyond a specified date when these records are used in their operations; (2) must retain all training records for a period of 12 months beyond when the person identified in the records continues to perform the duties for which the training was provided; (3) must make these records available to a duly authorized individual promptly upon oral or written request; (4) must keep required records as original records, true copies or as electronic records, which must be kept in accordance with part 11 (21 CFR part 11); and (5) may store specified records offsite after 6 months following the creation of the record, if the records can be retrieved and provided onsite within 24 hours of requests for official review. We also specified that all records required by this rule are subject to the disclosure requirements of part 20 (21 CFR part 20). In table 10, we describe revisions to proposed § 1.912 and following the table we respond to comments related to these provisions.

TABLE 10—§ 1.912 WHAT RECORD RETENTION AND OTHER RECORDS REQUIREMENTS APPLY TO SHIPPERS, RECEIVERS, LOADERS, AND CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?

Proposed section	Description	Revision
1.912	Records requirements for shippers and carriers	Add "receiver" and "loader" to be subject to certain records requirements.
1.912(a)	Records that shippers must retain to demonstrate that they provide information to carriers as a regular part of their operations for 12 months beyond when the shipper may need to provide such information.	Split requirement into 2 parts: (1) Requires shippers to retain records that demonstrate that they provide specifications and operating temperatures to carriers for 12 months beyond termination of the agreement with the carriers (2) Requires shippers to retain records of written agreements and procedures required by 1.908(b)(3), (4), and (5) for a period of 12 months beyond when the agreements and procedures are in use.
1.912(b)	Carriers must retain certain written agreements and records of written procedures for 12 months beyond when the agreements and procedures are in use.	Removed reference to retention of written agreements required by 1.908(d)(2)(ii) and redesignated 1.908(d) to (c).
1.912(c)	Carriers must retain training records for 12 months beyond when the person identified in records continues to perform the duties for which they were trained.	Revised "continues to perform" to "stops performing".
1.912(d)	Requires persons subject to the rule to retain written agreements assigning tasks covered by the rule for 12 months beyond the termination of the agreement.	New provision in the final rule.
1.912(e)	Requires covered parties which operate under ownership or control of a single legal entity must retain records of their written procedures for 12 months beyond when the procedures are in use.	New provision in the final rule.
1.912(f)	Requires that cover parties make all records available to duly authorized individuals upon request.	Adds "loaders" and "receivers" to this provision Provision was proposed as 1.912(d).

TABLE 10—§ 1.912 WHAT RECORD RETENTION AND OTHER RECORDS REQUIREMENTS APPLY TO SHIPPERS, RECEIVERS, LOADERS, AND CARRIERS ENGAGED IN TRANSPORTATION OPERATIONS?—Continued

Proposed section	Description	Revision
1.912(g)	Records must be kept as original records, true copies, or electronic records.	Remove the requirement that electronic records must be kept in accordance with part 11 of this chapter. Provision was proposed as 1.912(e).
1.912(h)	Clarifies that electronic records are exempt from the requirements of part 11.	New provision resulting from the change to 1.912(g).
1.912(i)	Allows for offsite storage of records after 6 months and clarifies that electronic records are onsite if they are accessible from an onsite location.	Remove "after 6 months following the date that the record was made" limitation for offsite storage of records. Provision was proposed as 1.912(f).
1.912(j)	All records subject to disclosure requirements of part 20	No change. Provision was proposed as 1.912(g).

(Comment 165) Several comments assert that we should exempt sanitary food transportation electronic records from compliance with part 11 and instead should take a more practical and simpler approach to requiring the authentication of electronic records. Some of these comments assert that requiring compliance with part 11 would be overly burdensome and cost-prohibitive and that this requirement is unnecessary because it would not significantly benefit the public health and is disproportionate to the regulatory need. Other comments assert that few, if any, entities engaged in the transportation of food would be able to meet this requirement because of the complexities involved with complying with part 11.

Some comments state complying with part 11 would mean that current electronic records and recordkeeping systems would have to be redesigned and would require the use of specialized and expensive software, which many small shippers, carriers and receivers might not be able to afford. Another comment states that compliance with the electronic records requirements in part 11 would be onerous for operations that currently use a combination of paper and electronic recordkeeping systems and that the effective integration of electronic recordkeeping systems throughout the food transportation chain might not be achievable given the diverse nature of the parties involved in the food transportation system and the different types of electronic systems that are currently used by the industry.

One comment acknowledges the importance of requiring that firms have adequate safeguards in place to ensure that electronic records cannot be altered, but asks us to provide the transportation industry with the flexibility to allow it to continue using, or to begin using, any existing electronic recordkeeping system that accomplishes this goal without mandating complete compliance with the prescriptive requirements in part 11. According to these comments, allowing the transportation industry to use existing electronic recordkeeping systems would enable industry to achieve our stated electronic recordkeeping goals efficiently and cost-effectively. A related comment urges us to provide a clear statement that companies may use any electronic recordkeeping systems as long as they ensure that all records are valid, accurate, and cannot be surreptitiously altered even if those electronic recordkeeping systems do not meet the prescriptive requirements of part 11.

(Response 165) We agree that redesigning large numbers of existing electronic records and recordkeeping systems would create a substantial burden disproportionate to the public health need. Therefore, we are providing in new § 1.912(g) of this final rule that records that are established or maintained to satisfy the requirements of this rule, and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. We also are specifying that records that satisfy the requirements of this rule, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. The rule provides that parties covered by this rule may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. We are also establishing a conforming change in part 11, as new § 11.1(n), which says that part 11 does not apply to records required to be established or maintained by this rule, and that records that satisfy the requirements of this rule, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

Although we are not specifying that part 11 applies, we expect parties covered by this rule to take appropriate measures to ensure that records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

(Comment 166) Some comments assert that the 12 month record retention requirement in proposed § 1.912(a) is unnecessary and burdensome. One comment states that the time and costs required to create and maintain records for this rule will far outweigh the benefits of collecting and storing the information. One comment states that requiring record retention for 12 months beyond the last date of the activity described by the record as set forth in proposed § 1.912(a) is confusing. The comment interprets the language of proposed § 1.912(a) as requiring perpetual record retention activity for persons covered by this rule by continually adding an additional 12 month record retention period beyond the latest requirement. The comment also states that the proposed requirement that carriers retain training records for a period of 12 months beyond when the person identified in such records continues to perform the duties for which the training was provided is confusing, and asks us to restate the requirement more clearly. The comment asks, for example, if a person receives a refresher training course 11 months after the initial training, and then receives another refresher training course 13 months later, all the while continuing to perform the duties for which the training was provided, how long must the original and refresher training records be retained?

(Response 166) We are requiring that records be retained for a period 12 months beyond the last date of the activity described by the record, so that we can review the past practices of a shipper or carrier that may not currently be engaged in food transportation operations. Maintaining such records on an ongoing basis will not be burdensome because the practices described in such records, *e.g.*, vehicle cleaning practices, procedures for providing information to shippers and carriers, etc., are likely to be ongoing operating practices that change very little over time. We therefore do not believe that further clarification of § 1.912(a) is necessary. With respect to refresher training, we would only expect records of the refresher training to be retained for our examination if such training was necessary for the person to continue to meet the training requirement of § 1.910(a). For example, if a carrier previously only transported food that does not require temperature control for safety, *e.g.*, was refrigerated strictly for quality purposes, and thus, not subject to this rule, but was beginning to transport shell eggs, it would be necessary to ensure that a vehicle operator was aware of the potential food safety problems and associated temperature control needs for shell egg transportation.

(Comment 167) A few comments commend our "practical approach" of not proposing that carriers or shippers would have to maintain a "roomful of records" documenting conditions for individual shipments. These comments state that while our generally practical approach has been conveyed to the food transportation industry repeatedly at FDA's public meetings, it was not discussed in detail in the preamble to the proposed rule. These comments encourage us to explain our regulatory philosophy in the preamble to this final rule in order to prevent deviations from our public statements in the future and to reinforce our intent. These comments also state that our field inspectors should be trained to understand that this regulation's recordkeeping requirements differ from the requirements under other FSMA regulations and that FDA inspectors should be trained not to ask for transportation records beyond those that are legally required under this final rule. A similar comment states that this rule is silent with respect to the retention of shipment records related to truck inspections, pre-cooling activities, and temperature monitoring, and asks us to make clear that the retention of such records is outside the scope of the rule.

(Response 167) Some of these comments refer to statements that we made in public meetings (Refs. 29 and, 30) in Chicago, IL and College Park, MD regarding the proposed rule.

In the Chicago meeting, for example, we stated: "[A] carrier will have to provide information to shippers if it's a bulk carrier, about prior cargoes in its vehicle. We're not looking for a record of every prior cargo that was transported in every bulk vehicle the carrier operates. What we want to see is an SOP, that's the carrier's record . . . that states how it provides this information to the shipper." We further stated during the Chicago meeting that: [W]e're not looking for operational records that are going to fill a room up to the ceiling—[for example,] time, temperature, strip chart recordings—for every transportation operation for refrigerated food or cleaning records for every bulk tanker, we're looking for a procedure from the carrier that describes how he will provide this information to the shipper." Finally, we also said during the Chicago public meeting that: "[W]e've done all that we can to minimize the burden of this recordkeeping requirement, but enable us to verify that this information exchange, which we think is an important part of sanitary transportation practices, is taking place." We stated during the College Park public meeting that: "[W]e are not looking for carriers to fill up some room with time-temperature strip chart recordings for every load of refrigerated food that they transport and show those records for every operation that they conduct to the FDA. We are looking for the carrier to, in the form of a record, provide FDA [with] records that demonstrate that they do conduct this information exchange with shippers, that they do provide, as a part of their operation, information about the maintenance of temperature control to shippers." We again emphasized during the College Park public meeting that we "tried to develop this recordkeeping provision in a way that minimizes the burden but recognizes the accountability of the carrier to demonstrate to shippers that they are transporting refrigerated foods or bulk foods under conditions that comply with requirements of the rule." Accordingly, these comments are correct in observing that the records retention requirements of this rule do not require carriers or shippers to maintain for our examination, records documenting conditions, such as temperature conditions, for individual shipments. Carriers may, however, choose to retain such information to provide to shippers upon request in accordance with § 1.908(e)(2)(i).

These comments also are correct in stating that this rule differs from other FSMA rules because this rule does not require the maintenance of records of ongoing transportation operations in the same way that some other FSMA rules require the retention of specific operating records. This rule, for example, does not mandate that persons covered by this rule must maintain monitoring records as does the FSMA preventive controls rules. We will ensure that our investigators are trained to understand the unique recordkeeping requirements of this rule.

Finally, there are no requirements in this rule concerning the retention of individual shipment records for our examination related to truck inspections, or precooling and temperature monitoring activities. Shippers and carriers, however, may choose to retain such information for business purposes.

(Comment 168) One comment states that the proposed rule requires carriers to demonstrate the temperature conditions that are maintained during transport, but fails to specify how long a carrier must maintain these temperature condition records.

(Response 168) A carrier may, but is not required to, create records of temperature conditions maintained during the transportation of food to provide to a shipper or a receiver upon request pursuant to § 1.908(e)(2)(i). This rule does not establish any retention time requirements for these optional temperature condition records.

(Comment 169) Some comments state that the proposed requirements to store records onsite are contrary to accepted and effective recordkeeping practices. Some of these comments state that companies frequently keep records of food safety activities, as well as transportation, cleaning, and training records at their corporate offices and not at operating facilities and asks us to allow this practice to continue. These comments also state that there is little practical difference between maintaining records onsite at food transportation facilities versus maintaining them offsite, for example, at corporate offices, provided that they can be provided to duly authorized individuals promptly upon an oral or written request, that is, within 24 hours.

(Response 169) We agree with this comment. Therefore, we have revised § 1.912(h) of this final rule to allow offsite storage of all records, except for the written procedures required by § 1.908(e)(6)(i), provided that the records can be retrieved and made available to us within 24 hours of a request for official review. As proposed, we will continue to require that the written procedures required by § 1.908(e)(6)(i) remain onsite as long as the procedures are in use in transportation operations. These written procedures comprise cleaning, sanitizing and inspection procedures for vehicles and equipment, and we believe that they would normally be kept on site because they are used in operations at the site. We are not requiring that carriers maintain records of their actual cleaning, sanitizing and inspection operations they perform on vehicles and equipment. We anticipate that many records will be stored electronically and therefore will be accessible from an onsite food transportation facility.

(Comment 170) A few comments state that it may be difficult for some carriers to promptly provide records, depending on what we mean by the term "promptly." The comment provided an example of a small carrier such as a motor vehicle owner/driver who might own a single motor vehicle used to transport food, who may not carry required records (*e.g.*, training records) while in transit and who might maintain the required records in a private residence. One of these comments asks us to apply reasonable and flexible records production timeframes in these circumstances.

(Response 170) We anticipate that, to the extent feasible, we will carry out records examinations at a carrier's fixed business location. If we were to determine for any reason that it is necessary to request records for examination from a small carrier while the carrier is in transit, we would not necessarily expect the carrier to have the records in its immediate possession, and would provide the carrier with a reasonable amount of time to provide the records. Similarly, if for any reason we were to request records that a carrier maintains at a private residence, we would take into account the circumstances of the of the transportation operation as they may affect the carrier's ability to produce the records promptly.

(Comment 171) One comment states that the records requirements of the proposed rule would be difficult to comply with because the shipper, carrier and receiver roles are not always easily identifiable when food is transported sequentially by more than one person between its point of origin and final destination.

(Response 171) We understand that the sequential shipment of food by multiple persons might involve many persons such as brokers, rail carriers, motor carriers, distributors, etc., and that the roles of these persons may vary from one circumstance to another. Therefore, we have revised this final rule to better define the persons who are subject to the requirements of this rule. As we explained in our response to Comment 70, we have revised the definition of the term "shipper" to clarify the scope of this definition. As we also discussed in our response to Comment 53, we have revised the definition of the term "carrier" to focus it more narrowly on the person who is responsible for the sanitary condition of the vehicle or transportation equipment used to transport food and to exclude from the definition, a person who is solely responsible for the movement of the vehicle or equipment. We believe the clarity we have added to the shipper, loader, carrier and receiver roles will make recordkeeping easier.

(Comment 172) Some comments state that written agreements assigning duties in compliance with this rule to other persons, as discussed in our response to Comment 16, should be subject to the record keeping provisions of this rule.

(Response 172) We agree. As we discussed in our response to Comment 16, we expect that the parties would have a written contract as proof of their agreement. To enable us to determine which party has responsibility to fulfill a duty assigned by this rule, we are establishing in § 1.912(b) that written agreements assigning duties in compliance with this rule are subject to the record keeping provisions of this rule.

(Comment 173) Some comments express concern that this rule's recordkeeping requirements will pose a burden on businesses. One of these comments states that this rule adds to other FDA records requirements. Another comment questioning the necessity of the records requirements of this rule, states that food transportation vehicles are pre-cooled and inspected before they are loaded and if they do not meet the required sanitary standards, they are refused or sent to be washed out and that this information is recorded in the shipping paperwork and can be provided to shippers, receivers, and FDA if necessary. Another comment acknowledges that it is important for a carrier to be able to demonstrate that a process is in place for training, sanitizing and cleaning, but asserts that retaining records that document these activities for one year would not serve any meaningful food transportation safety purpose.

(Response 173) We have made several revisions to this final rule in response to comments that we received on the proposed rule that will lessen the recordkeeping requirements for persons who are subject to the rule (see Comment 129, Comment 149, Comment 165, and Comment 169). Section 7202(b) of the 2005 SFTA requires us to issue a regulation that "require[s] shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated." Section 7202(c) also states that we must prescribe practices that we deem to be appropriate and necessary relating to, among other things, recordkeeping. As we have explained throughout the preamble to this final rule, we have determined that the records provisions in this final rule are appropriate for this purpose and required of us by our statutory mandate.

(Comment 174) One comment asks us to codify all of the recordkeeping requirements that apply to both the manufacture and transportation of animal feed in one location for ease of accessibility by the animal industry.

(Response 174) We have issued this rule for the sanitary transportation of human and animal food under the 2005 SFTA and the preventive controls rule for animal food under the FSMA, which are two separate grants of statutory authority given to us by Congress. These rules and their records requirements have been codified in distinct parts of Title 21 of the Code of Federal Regulations to reflect these two different authorizing statutes. However, FDA maintains a Web site dedicated to the FSMA, which can be found at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm*, from which industry can quickly access information about this sanitary food transportation rule and the other FSMA rules.

(Comment 175) One comment notes that records that are required by our seafood and juice HACCP rules are exempt from public disclosure under the Freedom of Information Act (FOIA), and asks us to similarly exempt the records required by this final rule from public disclosure. The comment's concern is that the records required by this rule may contain proprietary and confidential information (*e.g.*, contracts between carriers and shippers under proposed § 1.908(d)(2)(ii)), may contain information that could be used to compromise food safety measures (*e.g.*, carrier's written procedures for cleaning and inspecting vehicles and transportation equipment), and could be misunderstood if taken out of context.

(Response 175) We first note that in the rulemaking for the seafood and juice HACCP rules we did not state that records required by these rules are exempt from public disclosure. In this regard, the Agency concluded in the seafood HACCP final rule (60 FR 65096 at 65138), that HACCP plans, as a general rule, meet the definition of trade secret information, and thus, even if these plans are in Agency files, they likely would not be available under FOIA. However, because FDA is bound by FOIA and the Agency's implementing regulation in 21 CFR part 20, the Agency is unable to exclude categorically all HACCP records in Agency files from public disclosure.

We would determine whether records required by this rule that we copy are either publicly disclosable or protected from public release under the FOI Act on a case-by-case basis. We copy records on a case-by-case basis as necessary and appropriate. We primarily intend to copy such records if the preliminary assessment by our investigator during a routine inspection is that regulatory followup may be appropriate (*e.g.,* if these records demonstrate that cleaning procedures to maintain vehicles in appropriate sanitary condition are not being followed in a food transportation operation). We may consider it necessary to copy records when, for example, our investigators may need assistance in reviewing a certain record from relevant experts in headquarters. If we are unable to copy the records, we would have to rely solely on our investigators' notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. Even in these circumstances, however, certain information in the records could be considered confidential within the scope of the FOI Act and would be redacted from any records that would otherwise be publicly disclosable.

H. Waivers (§§ 1.914–1.934)

In table 11, we describe revisions to proposed §§ 1.914 to 1.934 and following the table we respond to comments related to these provisions.

TABLE 11—§§ 1.914 TO 1.934 WAIVERS

Proposed section	Description	Revision
1.914(a) and (b)	Under what circumstances will FDA waive a requirement of this subpart?	Replaced "FDA" with "we".
1.916	When will FDA consider whether to waive a requirement of this subpart?	Replaced "FDA" with "we".
1.918(a) and (b)	What must be included in the Statement of Grounds in a petition requesting a waiver?	No change.
1.920	What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?	No change.
1.922	Who will respond to a petition requesting a waiver?	No change.
1.924(a)–(d)	What process applies to a petition requesting a waiver?	No change.
1.926	Under what circumstances may FDA deny a petition requesting a waiver?	Replaced "FDA" with "we".
1.928	What process will FDA follow when waiving a requirement of this subpart on FDA's own initiative?	Replaced "FDA" with "we". Replaced "FDA" with "our".
1.930	When will a waiver granted by FDA become effective	Replaced "granted by FDA" with "that we grant".
1.932	Under what circumstances may FDA modify or revoke a waiver?	Replaced "FDA" with "we".
1.934(a)–(c)	What procedures apply if FDA determines that a waiver should be modified or revoked?	Replaced "FDA determines" with "we determine".

(Comment 176) A comment asks that we clarify how we would waive requirements if we determine that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that is in the public interest, and how we would communicate these waivers to state agencies.

(Response 176) In §§ 1.924 and 1.928 of the proposed rule, we outlined the processes we will follow when waiving a requirement of this subpart, depending on whether the waiver is granted in response to a submitted petition or on our own initiative. In both cases, we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver. We believe this explanation is clear; therefore, we are retaining the language in §§ 1.924 and 1.928 in this final rule. Additionally, publication in the **Federal Register** provides notice to all interested parties, including State and Tribal agencies.

(Comment 177) Some comments support our proposal to include in the final rule a petition process whereby we can grant a waiver from the proposed requirements of this rule. Additionally, a few comments urge us to not make such a petition too onerous or burdensome for individuals, small shippers, and owner/operator carriers and to provide lenience and guidance for such situations.

(Response 177) We agree that we should allow a petition process to grant waivers from the requirements of this rule. In § 1.916 of the proposed rule, we stated that we will consider whether to waive a requirement of this rule on our own initiative or on a petition submitted under 21 CFR 10.30. In proposed § 1.918 we outlined what must be included in the Statement of Grounds in the petition. And in proposed § 1.924 we outlined the process that will apply to a petition requesting a waiver. We do not believe that the petition described in § 10.30, the Statement of Grounds described in § 1.918, or the process described in § 1.924 is onerous or burdensome and, therefore, are retaining the language in these sections in the final rule. We do not plan to publish guidance on the petition itself, since it is explained in detail in 21 CFR 10.30.

(Comment 178) A comment strongly urges that we issue public notice of potential waivers and petitions for waivers in the **Federal Register** and allow public comment on each proposed waiver. The comment states that our proposed system of granting waivers for some sanitary transportation requirements without first soliciting public comment is inconsistent with the FD&C Act and the Administrative Procedures Act (APA), since the FD&C Act requires the Secretary to publish waivers and any reasons for the waiver in the **Federal Register** (21 U.S.C. 350e(d)(2)). The comment states that this demonstrates Congress's intent to have the public involved in the waiver process and notes that FDA itself recognized that public comment may be necessary to inform its determination whether to grant a waiver (79 FR 7006 at 7029).

(Response 178) We will consider whether to waive a requirement of this subpart in one of two ways: (1) On a petition submitted under 21 CFR 10.30 or (2) on our own initiative. For a filed petition, § 1.924(b) states that we will publish a notice in the **Federal Register** requesting information and views on the petition, including information and views from persons who could be affected by the waiver if the petition were to be granted. For waivers to be established on our own initiative, § 1.928 states that we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver. We disagree that our system of granting waivers for some sanitary transportation requirements without first soliciting public comment is inconsistent with the FD&C Act and the APA. As we discussed in the proposed rule (79 FR 7006 at 7028), when we have determined that a waiver is appropriate in accordance with the standard set forth in section 416(d)(1) of the FD&C Act and proposed § 1.914, we may grant a waiver without first soliciting public comment. We have concluded that this process is sufficient for us granting a waiver on our own initiative because it is the process set forth in section 416(d)(2) of the FD&C Act.

(Comment 179) Some comments recommend that we expedite written responses to waiver petitions and include in the final rule a timeframe for our decision on a petition (*e.g.,* 180 days) and steps to be taken if the deadline is missed.

(Response 179) We disagree with these comments. In proposed § 1.924, we stated that the procedures set forth in 21 CFR 10.30 govern our response to a petition requesting a waiver. 21 CFR 10.30 outlines the petition process and states that we will respond to the petitioner within 180 days of receipt of the petition. 21 CFR 10.30 does not address steps to be taken if the 180-day timeframe is missed.

(Comment 180) Some comments request that we establish a waiver application process that resembles the process for granting a variance under the proposed FSMA produce safety regulation and ensures engagement with the applicant. One of the comments suggests that this process provide an avenue for an industry or a person to request a waiver without the involvement of a state or foreign government. These comments also state that the process should include an opportunity to re-obtain a revoked waiver after a period of time to incentivize long-term commitments to food safety improvement.

(Response 180) The process for granting a variance under the FSMA produce safety rule is very similar to the waiver petition process described in §§ 1.914 to 1.934 of this final rule. Both require the submission of a petition under 21 CFR 10.30, and both require that we publish a notice in the **Federal Register** requesting information and views on the filed petition. Also, in both cases, we will respond to the petitioner in writing and also will make public a notice on our Web site announcing our decision to either grant or deny the petition. Much of the rest of the processes are similar, as well. Both ensure our engagement with the applicant by requiring us to provide a written response to the applicant. Additionally, the process in this final rule does not require involvement of a state or foreign government. Finally, while the waiver petition process doesn't specifically address the opportunity to re-obtain a revoked waiver, it does not preclude an interested party from reapplying for a revoked waiver using the petition process described in this final rule.

(Comment 181) Some comments request clarification regarding whether a waiver can be revoked in whole or part from the group to which it was granted. A few comments suggest that we develop a policy that would allow us to revoke a waiver from a single "bad actor," even when the waiver has been granted to an entire industry. The comments state that by doing so, each member of the industry still maintains individual responsibility for ensuring compliance.

(Response 181) We outlined the process we will follow for modification and revocation of waivers in §§ 1.932 and 1.934 of the proposed rule. Specifically, we stated in § 1.932 that we may modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest. We believe the language in §§ 1.932 and 1.934 is clear and, therefore, are retaining it in the final rule. We do not agree that we should establish a policy for revoking a waiver from a single firm. The Sanitary Food Transportation Act of 2005 states that "the Secretary may waive any requirement under this section, with respect to any class of persons, vehicles, food, or nonfood products . . . ." Since the SFTA gives FDA the authority to issue waivers to cover any class of persons, vehicles, food, or nonfood products, we believe that revocation of a waiver must also cover that same class of persons, vehicles, food, or nonfood products to which it was issued and not a subset thereof. Nonetheless, FDA can take appropriate action against an individual firm, such as described by this comment, if the firm fails to comply with the requirements of this rule.

(Comment 182) A comment urges us to adopt appropriate provisions in the regulation governing waivers to protect against the disclosure of confidential business information of shippers, carriers, and receivers.

(Response 182) We have adopted appropriate provisions in this regulation related to protection of confidential information. Proposed § 1.920 states that we will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under 21 CFR part 20 and would be made public as part of the docket associated with this request. As we stated in the proposed rule, we do not believe that information exempt from disclosure under 21 CFR part 20 is the type of information that we are requiring to be submitted in such a petition or that would be relevant in any comments submitted on such a petition. We will publicly disclose a petition for waiver or comments on such a petition unless information in those documents falls within the exemption for confidential commercial or trade secret information in 21 CFR part 20.

(Comment 183) A few comments suggest that we provide a window of 60 days for industry to come into compliance with the regulation when a waiver is revoked. The comments state that regulators could increase food safety surveillance of the product or industry during this short time.

(Response 183) We disagree with these comments. In proposed § 1.934(a)(2) we stated that we will publish a notice of our determination that a waiver should be revoked in the **Federal Register.** We believe that this will serve as a notification to the affected industry that we are considering revocation of the waiver and will allow affected parties to plan for changes, should the waiver, in fact, be revoked. Therefore, we are retaining this language in the final rule. After considering written comments on the revocation notice, we will publish our decision in the **Federal Register.** The effective date of the revocation will be the date of publication of the notice.

V. Effective and Compliance Dates

A. Effective and Compliance Dates for Part 1, Subpart O

We proposed that any final rule based on proposed part 1, subpart O become effective 60 days after its date of publication in the **Federal Register**, with staggered compliance dates (79 FR 7006 at 7032). Businesses other than small businesses would have 1 year from the date of publication of the final rule to comply with the rule, whereas small businesses would have 2 years to comply with the rule.

After considering the following comments addressing the proposed compliance dates for this rule, we are establishing the effective and compliance dates as proposed.

(Comment 184) One comment encourages us to allow a phased-in timeframe for compliance with this rule because companies will need time to develop written protocols and train company personnel. One comment states that it is not reasonable to expect the industry to be in compliance in 1 or 2 years, given the cultural changes required by the proposed regulation. One comment states that the 2-year period for compliance for small businesses seems overly generous because many, if not most, of the requirements of this rule should already be in place under existing rules and regulations. A comment states that it will be difficult to implement phased-in compliance dates because inspectors will not be able to determine a business' size when performing single vehicle inspections. The comment recommends that we establish a single compliance date that is possible for all businesses to meet.

(Response 184) It is our general practice for this type of rulemaking, which does not address a public health emergency or other matter that would require a uniform compliance date for all businesses, to consider business size in establishing timeframes for businesses to come into compliance with the rule. After considering these comments, we are retaining the proposed compliance dates for this rule, *i.e.,* 1 year after the date of publication of the final rule for businesses other than small businesses, and 2 years after the date of publication of the final rule for small businesses, because we believe that they are reasonable for businesses subject to this rule. We do expect that questions, such as how would an inspector determine a business' size, may arise during the implementation of this rule. We intend to work closely with the food transportation industry, extension and education organizations, and State, local, and tribal partners to facilitate implementation of this rule. Furthermore, this rule is based upon industry best practices already in place, which should minimize the time for industry to come into compliance.

B. Effective Dates for Conforming Changes

The conforming amendment to part 11 adds a reference to the scope of part 11 that the records required under part 1, subpart O are not subject to part 11. This conforming amendment is effective on June 6, 2016, the same date as the effective date of part 1, subpart O. We are not establishing compliance dates for these conforming amendments. As a practical matter, compliance dates will be determined by the dates for compliance with part 1, subpart O.

VI. Executive Order 13175

In accordance with Executive Order 13175, FDA has consulted with tribal government officials. A Tribal Summary Impact Statement has been prepared that includes a summary of tribal officials' concerns and how FDA has addressed them (Ref. 31). Persons with access to the Internet may obtain the Tribal Summary Impact Statement at *http://www.fda.gov* or at *http://www.regulations.gov.* Copies of the Tribal Summary Impact Statement also may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). We believe that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule defines small business as one subject to this rule employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to this rule having less than $27,500,000 in annual receipts. The Agency concludes that the final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that would meet or exceed this amount.

The final analysis conducted in accordance with these Executive orders and statutes is available in the docket for this rulemaking (Ref. 24) and at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

VIII. How does the Paperwork Reduction Act of 1995 apply to this final rule?

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Sanitary Transportation of Human and Animal Food.

Description: This new collection of information will be performed by shippers, receivers, loaders, and carriers of human and animal food. The records requirements of this final rule include records pertaining to: Sanitary specifications, temperature during transportation operations, cleaning of bulk vehicles, training, and written procedures. In addition, this final rule includes submission requirements pertaining to waiver petitions, when appropriate.

We have concluded that recordkeeping and submissions are necessary for the success of the food transportation operation. Records of actions taken due to each requirement are essential for manufacturers to implement this rule effectively. Further, records and reports are essential for us to be able to determine whether a firm is in compliance with the rule.

Analysis of Burden Estimates Resulting From This Final Rule

Description of Respondents: Shippers, receivers, loaders, and carriers of human and animal food.

In the following paragraphs, we describe and respond to the comments that we received on the PRA for our 2014 proposed rule. We numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 185) We received many comments regarding the burden of proposed § 1.908(d)(2)(i), which required demonstration of temperature conditions during a shipment. The comments stated that these burdens can include adoption of a method of monitoring and recording temperatures during shipment, purchase of equipment, implementation of those systems, and the costs of downloading data. One comment stated that, although most carriers have temperature data on temperature-controlled shipments, this data is not readily available and easily retrievable without incurring significant costs. Furthermore, as another comment stated, if the proposed requirement were finalized, far more than the 1 percent of industry estimated in the economic analysis would have to incur these costs. Another comment stated that, while "reefer" trailers are generally equipped with thermometers, they do not ordinarily create any kind of permanent printout record to be shown to the receiver. The comment emphasized that any requirement to have this would put unnecessary burdens on industry, particularly small firms. One comment stated that the current practice is for such records to be provided only if there is an indication of a problem (*i.e.*, signs of temperature abuse) upon receipt of the load.

(Response 185) We acknowledge the lack of data available to us when estimating the cost of this proposed requirement. However, as a result of public comment, this requirement has been amended (final § 1.908(e)(2)(i)) to require this demonstration of temperature conditions only when the carrier has agreed by contract with the shipper to assume this responsibility, and only if requested by the shipper or receiver and in a way agreeable to the shipper and carrier, which can include measurements of ambient temperature. We believe this is aligned with current industry practices and is not estimated to represent new cost to industry.

(Comment 186) One commenter stated that proposed § 1.908(d)(4), requiring carriers offering bulk vehicles for food transportation to provide written documentation to the shipper that identifies the three previous cargoes transported in the vehicle, would be overly burdensome. Another comment stated that the estimated burden of this requirement did not include the cost of implementing industry-wide software changes for railroads, as tracking this information is not current industry practice.

(Response 186) These comments did not provide any data to allow us to calculate this burden, and we acknowledge the simplicity of our assumptions in the estimations of the cost related to this provision. However, in response to comments on the proposed rule, this provision has been amended (final § 1.908(e)(4)) to require carriers to provide information identifying the last previous cargo only when they have agreed by contract with the shipper to assume this responsibility, and *only if requested* by the shipper. We believe this provision is aligned with current industry practice. No new burden is estimated for this information collection.

(Comment 187) A commenter stated that proposed § 1.908(d)(5), which required carriers to provide information to shippers describing the most recent cleaning of bulk vehicles, would be beyond the current capabilities of railroads. The comment stated that compliance with this requirement would likely require expensive investments to track this information, as this is not current industry practice.

(Response 187) This comment did not provide any data that would allow us to estimate this burden. However, in response to comments on the proposed rule, this provision has been amended (final § 1.908(e)(5)) to require information describing the most recent cleaning of bulk vehicles only when the carrier has agreed by contract with the shipper to assume this responsibility, and only if requested by the shipper. This provision is believed to be aligned with current industry practice. No new burden is estimated for this information collection.

(Comment 188) One commenter stated that requiring firms to retain records for 1 year would not benefit those along the supply chain and would be unnecessarily burdensome.

(Response 188) This comment does not describe how the 12-month retention requirement would be more burdensome. This final rule reduces the total number of records related to sanitary food transport, which will reduce new burden to industry. Furthermore, the codified provides a wide range of options on how these records must be kept. We estimate that firms will maintain electronic records, which further reduces burden.

(Comment 189) One comment expressed appreciation regarding the ability of industry to diverge from certain proposed requirements, such as those for bulk shipments, by contractual agreement. This comment stated that reflects a practical understanding of the way business is conducted and how flexibility is essential because of the highly complex nature of the transportation chain. This comment went on to state that FDA should permit flexibility to allow businesses to enter into contractual agreements allocating the responsibilities for shippers, carriers, and receivers to other parties.

(Response 189) While this comment did not address the PRA of the proposed rule specifically, it does allow us to estimate that contractual agreements, such as those addressed in § 1.908(b)(3), are common business practice. No additional information collection burden to industry is estimated for such agreements.

FDA estimates the burden of this collection of information as follows:

The total one-time estimated burden imposed by this collection of information is 254,923 hours (228,832 recordkeeping hours + 144 submission hours + 25,947 third-party disclosure hours). The total annual estimated burden imposed by this collection of information is 120,342 hours (120,163 recordkeeping hours + 48 submission hours + 113 third-party disclosure hours). There are no capital costs or operating and maintenance costs associated with this collection of information. FDA estimates that firms will be able to fulfill recordkeeping requirements with existing record systems; that is, FDA estimates that it will not be necessary for firms involved in food transportation to invest in new recordkeeping systems.

One-time burdens are estimated for establishing written procedures regarding integrated transportation operations, written procedures for transportation operations with respect to sanitary condition of vehicles and equipment, previous cargoes, and adequate temperature control; written procedures for cleaning and sanitizing; procedures for use of bulk vehicles; training; notification of operating temperature and written sanitary specifications, disclosure of information; and submission of waiver petitions, when appropriate. Annual burdens are related to disclosure of written sanitary specifications, operating temperatures, and training records.

First-year and annual burdens related to recordkeeping requirements are presented in table 12. In the economic analysis of this final rule, cost estimations were estimated based on a percentage of, for example, shippers that may have to change behavior as a result of this final rule, or shipments that would have new records associated with them. Calculating percentages of firms or shipments often resulted in fractions; these numbers were rounded to the nearest whole number to be presented in the analysis. Therefore, any discrepancies in table 12 are attributable to rounding.

It is estimated that about 343 recordkeepers will each spend 2 hours (one-time) developing written procedures related to integrated transportation operations, as required by § 1.908(a)(4). Therefore, 343 × 2 = 686 (686.13) one-time hours, as presented in line 1.

The one-time cost of developing written procedures to ensure sanitary condition of vehicles and equipment, as required by § 1.908(b)(3), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour adjusting current practices with respect to this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(3), as shown in line 2.

The one-time cost of developing written procedures to ensure that previous cargo does not make food unsafe, as required by § 1.908(b)(4), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour adjusting current practices with respect to this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(4), as shown in line 3.

The one-time cost of developing written procedures to ensure that food is transported under adequate temperature control, as required by § 1.908(b)(5), is estimated at the shipper level. It is estimated that these written procedures are relatively simple and easy to assemble, and that one recordkeeper for about 4,483 firms will spend 0.5 hour aligning current practices with this requirement. Therefore, 0.5 hours × 4,483 = 2,242 (2,241.69) one-time hours for § 1.908(b)(5), as shown in line 4.

The one-time cost of development of written procedures related to cleaning and sanitation, as required by § 1.908(e)(6)(i), is estimated at the carrier level. It is estimated that one recordkeeper for about 37,249 firms will spend 2 hours developing written procedures. Therefore, 2 hours × 37,249 = 74,498 (74,498.48) one-time hours for § 1.908(e)(6)(i), as shown in line 5.

The one-time cost of development of written procedures related to bulk vehicles, as required by § 1.908(e)(6)(iii), is estimated at the bulk carrier level. It is estimated that one recordkeeper for about 6,713 firms will spend 2 hours developing written procedures. Therefore, 2 hours × 6,713 = 13,426 (13,426.48) one-time hours for § 1.908(e)(6)(iii), as shown in line 6.

The one-time cost of establishing training records, as required by § 1.910(b), is estimated at the employee level. It is estimated that one recordkeeper will establish a record for about 1,668,698 workers, and this will take 5 minutes (0.08 hours) for each worker. Therefore, 0.08 hour × 1,668,698 = 133,496 (133,495.86) one-time hours for § 1.910(b), as shown in line 7.

The total one-time hourly recordkeeping burden is 228,832 (228,832.02) hours.

The annual cost of training records, as required by final § 1.910(b), is estimated at the worker level. It is estimated that one recordkeeper for each of about 1,502,032 workers will spend 5 minutes (0.08 hour) minutes completing records related to annual training (the time spent training is estimated separately and not included in this PRA analysis). We believe recordkeeping will be very simple and can consist of, for example, printing off a certificate of completion. Therefore, 0.08 hour × 1,502,032 workers = 120,163 (120,162.59) annual hours for § 1.910(b), as shown in line 8. Therefore, the annual hourly recordkeeping burden is 120,163 hours.

TABLE 12—FIRST YEAR ONLY AND ANNUAL RECORDKEEPING BURDENS

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
First Year Only Hourly Burden					
1. Written Procedures for Integrated Operations (1.908(a)(4))	343	1	343	2	686 (686.13)
2. Written procedures to ensure sanitary condition of vehicles (1.908(b)(3))	4,483	1	4,483	0.5	2,242 (2,241.69)
3. Written procedures to ensure that previous cargo does not make food unsafe (1.908(b)(4))	4,483	1	4,483	0.5	2,242 (2,241.69)
4. Written procedures to ensure that food is transported under adequate temperature control (1.908(b)(5))	4,483	1	4,483	0.5	2,242 (2,241.69)
5. Written procedures, cleaning and sanitation (1.908(e)(6)(i))	37,249	1	37,249	2	74,498 (74,498.48)
6. Written procedures, bulk vehicles (1.908(e)(6)(iii))	6,713	1	6,713	2	13,426 (13,426.48)
7. Training Records (1.910(b))	1,668,698	1	1,668,698	0.08	133,496 (133,495.86)
First Year Only Hourly Recordkeeping Burden					228,832 (228,832.02)

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Recurring Hourly Burden					
8. Training Records (1.910(b))	1,502,032	1	1,502,032	0.08	120,163 (120,162.59)
Annual Hourly Recordkeeping Burden					120,163 (120,162.59)

The one-time and annual hourly burdens related to submission of waiver petitions (§ 1.914) are presented in table 13. This final rule refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in § 10.30 have been approved under OMB control number 0910–0183 (General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions).

In the first year, it is estimated that one recordkeeper from each of a total of six firms will each spend 24 hours submitting a waiver petition to FDA (per the estimate for the petition process in § 10.30, approved and estimated under OMB control number 0910–0183 as 24 hours per submission). Therefore, 6 waiver petitions × 24 hours = 144 one-time hours for § 1.914, as shown in line 1. Annually, it is estimated that one recordkeeper from each of a total of two firms will spend 24 hours submitting a waiver petition to FDA. Therefore, 2 waiver petitions × 24 hours = 48 annual hours for § 1.914, as shown in line 2.

TABLE 13—FIRST YEAR AND ANNUAL SUBMISSION BURDEN

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated First Year Only Submission Burden					
1. Waiver Petitions (1.914)	6	1	6	24	144

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated Annual Submission Burden					
2. Waiver Petitions (1.914)	2	1	2	24	48

The one-time and hourly burdens related to third-party disclosures are presented in table 14. The one-time cost of developing written sanitary specifications necessary for transportation, as required by § 1.908(b)(1), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 10,163 firms will spend 30 minutes developing written sanitary specifications. Therefore, 0.5 hour × 10,163 firms = 5,082 (5,081.57) one-time hours for § 1.908(b)(1), as shown in line 1.

The one-time cost of developing initial notifications of operating temperature, as required by § 1.908(b)(2), is estimated at the shipper level. It is estimated that one recordkeeper for each of about 5,646 firms will spend 30 minutes (0.5 hour) developing these notifications. Therefore, 0.5 hour × 5,646 firms = 2,823 (2,823.13) hours, as shown in line 2.

The one-time cost of establishing records pertaining to disclosure of information, as required by § 1.912(a), is estimated at the firm level. It is estimated that one recordkeeper will establish a record at a total of about 36,084 firms, and this will take 30 minutes (0.5 hour) for each record. Therefore, 0.5 hour × 36,084 = 18,042 (18,041.88) one-time hours for § 1.912(a), as shown in line 3.

The total one-time hourly third-party disclosure burden is 25,947 (25,946.57) hours.

The annual cost of disclosing necessary sanitary specifications, as required by § 1.908(b)(1), is estimated at the firm level. It is estimated that 1 recordkeeper for each of about 226 firms will spend 5 minutes disclosing sanitary specifications. Therefore, 0.08 hour × 226 shipments = 18 (18.07) annual hours for § 1.908(b)(1), as shown in line 4.

The annual cost of disclosing operating temperature conditions, as required by § 1.908(b)(2), is estimated at the shipper level. It is estimated that 1 recordkeeper for each of about 226 firms will spend 30 minutes (0.5 hour) disclosing necessary temperature conditions. Therefore, 0.5 hour × 226 firms = 113 (112.93) annual hours for § 1.908(b)(2), as shown in line 5.

The total annual hourly third-party disclosure burden is 131 (130.99) hours.

TABLE 14—THIRD-PARTY DISCLOSURE BURDEN

21 CFR section	Number of recordkeepers	First year frequency of recordkeeping	Total records	Hours per record	Total hours
Estimated First Year Only Third-Party Disclosure Burden					
1. Written Sanitary Specifications (1.908(b)(1))	10,163	1	10,163	0.5	5,082 (5,081.57)
2. Notification of operating temperature (1.908(b)(2))	5,646	1	5,646	0.5	2,823 (2,823.13)
3. Records pertaining to disclosure of information (1.912(a))	36,084	1	36,084	0.5	18,042 (18,041.88)
Total					25,947 (25,946.57)
Estimated Annual Third-Party Disclosure Burden					
4. Sanitary Specifications (1.908(b)(1))	226	1	226	0.08	18 (18.07)
5. Operating temperature conditions (1.908(b))(2)	226	1	226	0.5	113 (112.93)
Total					131 (130.99)

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. What is the environmental impact of this rule?

We have determined, under 21 CFR 25.30(j), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment (Refs. 32 and 33). Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. What are the federalism impacts of this rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132 on federalism. We have examined the effects of the requirements of this rule on the relationship between the Federal Government and the States. We conclude that Federal preemption of State or local rules that establish requirements for the sanitary transportation of human and animal food such that: (1) Complying with the requirements of the State or political subdivision and with a requirement of section 416 of the FD&C Act, or with this rule, is not possible; or (2) the requirements of the State or political subdivision, as applied or enforced, is an obstacle to accomplishing and carrying out section 416 of the FD&C Act or this rule, is consistent with this Executive order. FDA has not incorporated text in this rule to reflect this preemptive effect because section 416(e) of the FD&C Act expressly provides for this preemption.

Section 3(b) of Executive Order 13132 recognizes that Federal action limiting the policymaking discretion of States is appropriate "where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." The constitutional basis for FDA's authority to regulate food safety is well established. Section 4(a) of Executive Order 13132 expressly contemplates preemption where the exercise of State authority conflicts with the exercise of Federal authority under a Federal statute. Moreover, section 4(b) of Executive Order 13132 authorizes preemption of State law by rulemaking when the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute, or there is clear evidence to conclude that Congress intended the Agency to have the authority to preempt State law.

Section 4(e) of the Executive order provides that, "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." As required by the Executive order, FDA provided the States and local governments with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on February 5, 2014 (79 FR 7006). In the proposal, FDA specifically described this preemptive effect. In addition, we held three public meetings during the comment period for the proposed rule to discuss the provisions of the rule, answer questions, and solicit comments from stakeholders, including from State and local government representatives. Meetings were held February 27, 2014, in Chicago, IL; March 13, 2014, in Anaheim, CA; and March 20, 2014, in College Park, MD.

We received comments on the proposed rule from several State government agencies. Most of these comments addressed matters in this rulemaking other than the issue of preemption of State and local requirements for the sanitary transportation of human and animal food. One comment stated that the preemptive provision of section 416(e)(1) or (2) of the FD&C Act could function to prevent States from developing a unified sanitary transportation regulation that would address all modes of transportation. However, a State law, including unified State laws, should states wish to adopt such laws, concerning the sanitary transportation of food by motor vehicle or rail vehicle, is not preempted if such laws do not fall under either section 416(e)(1) or (2) of the FD&C Act. Furthermore, it is highly unlikely that any State law addressing transportation operations not subject to the 2005 SFTA, *e.g.*, barge transport, would fall within the scope of the 2005 SFTA's preemption provision. In conclusion, we have determined that the preemptive effects of this final rule are consistent with Executive Order 13132.

XI. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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3. FDA Memorandum, "Memoranda of Outreach," 2015.
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7. Michigan Department of Agriculture, "Food Truck Assessment Project, April 18/19, 2006."
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9. Caledonia Record, "DMV Stops Truck, Finds Spoiled Food," August 18, 2012.
10. Courier Journal, "Overheated Transport Trucks Spark Concerns About Spoilage," August 10, 2012.
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13. Tulsa World, "Food Carriers Doubling as Garbage Trucks," June 11, 1989.
14. Philly.com, "Food Trucks Can't Haul Waste in PA," March 14, 1990.
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16. FDA, "Guidance for Industry: Sanitary Transportation of Food," (*http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm208199.htm*), accessed and printed on December 16, 2015.
17. FDA, "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors: Food Security Preventive Measures Guidance," (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083049.htm*), accessed and printed on December 17, 2015.
18. FDA, "Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guide," (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm083075.htm*), accessed and printed on December 17, 2015.
19. Memorandum of Understanding Between The Food Safety and Inspection Service, United States Department of Agriculture, and The Food and Drug Administration, United States Department of Health and Human Services," (*http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm117094.htm*), accessed and printed on December 16, 2015.
20. "Guidance for Industry: Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food (Edition 5)," (*http://www.fda.gov/Food/GuidanceRegulation/ucm292746.htm*), accessed and printed on December 16, 2015.
21. Consent Decree, *Center for Food Safety* v. *Hamburg,* No. 12–cv–04529–PJH (N.D. Cal. February 20, 2014), (*http://www.centerforfoodsafety.org/files/2014-2-20-dkt-82-1-joint-consent-decree_26503.pdf*), accessed and printed on December 16, 2015.
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31. FDA, Tribal Impact Summary Statement, 2016.
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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342i, 343, 350c, 350d, 350e, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Add subpart O, consisting of §§ 1.900 through 1.934, to part 1 to read as follows:

Subpart O—Sanitary Transportation of Human and Animal Food

General Provisions

Sec.
1.900 Who is subject to this subpart?
1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?
1.904 What definitions apply to this subpart?

Vehicles and Transportation Equipment

1.906 What requirements apply to vehicles and transportation equipment?

Transportation Operations

1.908 What requirements apply to transportation operations?

Training

1.910 What training requirements apply to carriers engaged in transportation operations?

Records

1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

Waivers

1.914 Under what circumstances will we waive a requirement of this subpart?
1.916 When will we consider whether to waive a requirement of this subpart?
1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?
1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?
1.922 Who will respond to a petition requesting a waiver?
1.924 What process applies to a petition requesting a waiver?
1.926 Under what circumstances may we deny a petition requesting a waiver?
1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?
1.930 When will a waiver that we grant become effective?
1.932 Under what circumstances may we modify or revoke a waiver?
1.934 What procedures apply if we determine that a waiver should be modified or revoked?

Subpart O—Sanitary Transportation of Human and Animal Food

General Provisions

§ 1.900 Who is subject to this subpart?

(a) Except for non-covered businesses as defined in § 1.904 and as provided for in paragraph (b) of this section, the requirements of this subpart apply to shippers, receivers, loaders, and carriers engaged in transportation operations whether or not the food is being offered for or enters interstate commerce. The requirements of this subpart apply in addition to any other requirements of this chapter that are applicable to the transportation of food, *e.g.*, in 21 CFR parts 1, 117, 118, 225, 507, and 589.

(b) The requirements of this subpart do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations:

(1) Of food that is transshipped through the United States to another country; or

(2) Of food that is imported for future export, in accordance with section 801(d)(3) of the Federal Food, Drug, and Cosmetic Act, and that is neither consumed nor distributed in the United States; or

(3) Of food when it is located in food facilities as defined in § 1.227 of this chapter, that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.902 How do the criteria and definitions in this subpart apply under the Federal Food, Drug, and Cosmetic Act?

(a) The criteria and definitions of this subpart apply in determining whether food is adulterated within the meaning of section 402(i) of the Federal Food, Drug, and Cosmetic Act in that the food has been transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations under conditions that are not in compliance with this subpart.

(b) The failure by a shipper, carrier by motor vehicle or rail vehicle, loader, or receiver engaged in transportation operations to comply with the requirements of this subpart is a prohibited act under section 301(hh) of the Federal Food, Drug, and Cosmetic Act.

§ 1.904 What definitions apply to this subpart?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part. The following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Animal food means food for animals other than man, and includes pet food, animal feed, and raw materials and ingredients.

Bulk vehicle means a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, or any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

Carrier means a person who physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Cross-contact means the unintentional incorporation of a food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act into food, except animal food.

Farm has the meaning given in § 1.227 of this chapter.

Food not completely enclosed by a container means any food that is placed into a container in such a manner that it is partially open to the surrounding environment. Examples of such containers include an open wooden basket or crate, an open cardboard box, a vented cardboard box with a top, or a vented plastic bag. This term does not include food transported in a bulk vehicle as defined in this subpart.

Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business is a small business. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (*i.e.*, 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.

Loader means a person that loads food onto a motor or rail vehicle during transportation operations.

Non-covered business means a shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the 3-year period preceding the applicable calendar year. For the purpose of determining an entity's 3-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

Operating temperature means a temperature sufficient to ensure that under foreseeable circumstances of temperature variation during transport, *e.g.,* seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops, the operation will meet the requirements of § 1.908(a)(3).

Pest means any objectionable animals or insects including birds, rodents, flies, and larvae.

Receiver means any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

Shipper means a person, *e.g.,* the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Small business means a business employing fewer than 500 full-time equivalent employees except that for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to § 1.900(a) having less than $27,500,000 in annual receipts.

Transportation means any movement of food in by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment means equipment used in food transportation operations, *e.g.,* bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities that are performed by a farm.

Vehicle means a land conveyance that is motorized, *e.g.,* a motor vehicle, or that moves on rails, *e.g.,* a railcar, which is used in transportation operations.

Vehicles and Transportation Equipment

§ 1.906 What requirements apply to vehicles and transportation equipment?

(a) Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, *i.e.,* adulterated within the meaning of section 402(a)(1), (2), and (4) of the Federal Food, Drug, and Cosmetic Act during transportation operations.

(b) Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.

(c) Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.

(d) Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations.

Transportation Operations

§ 1.908 What requirements apply to transportation operations?

(a) *General requirements.* (1) Unless stated otherwise in this section, the requirements of this section apply to all shippers, carriers, loaders, and receivers engaged in transportation operations. A person may be subject to these requirements in multiple capacities, *e.g.,* the shipper may also be the loader and the carrier, if the person also performs the functions of those respective persons as defined in this subpart. An entity subject to this subpart (shipper, loader, carrier, or receiver) may reassign, in a written agreement, its responsibilities under this subpart to another party subject to this subpart. The written agreement is subject to the records requirements of § 1.912(d).

(2) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements in this subpart must be assigned to competent supervisory personnel.

(3) All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including:

(i) Taking effective measures such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.

(ii) Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.

(iii) Taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature control.

(4) The type of food, *e.g.,* animal feed, pet food, human food, and its production stage, *e.g.,* raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.

(5) Shippers, receivers, loaders, and carriers, which are under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of paragraphs (b), (d), and (e) of this section may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food consistent with the requirements of this section. The written procedures are subject to the records requirements of § 1.912(e).

(6) If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate action including, as necessary, communication with other parties to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

(b) *Requirements applicable to shippers engaged in transportation* *operations.* (1) Unless the shipper takes other measures in accordance with paragraph (b)(3) of this section to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* that will prevent the food from becoming unsafe, the shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any specific design specifications and cleaning procedures. One-time notification shall be sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(2) Unless the shipper takes other measures in accordance with paragraph (b)(5) of this section to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, a shipper of such food must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase. One-time notification shall be sufficient unless a factor, *e.g.,* the conditions of shipment, changes, necessitating a change in the operating temperature, in which case the shipper shall so notify the carrier in writing before the shipment. The information submitted by the shipper to the carrier is subject to the records requirements in § 1.912(a).

(3) A shipper must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, *i.e.,* will prevent the food from becoming unsafe during the transportation operation. Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a).

(4) A shipper of food transported in bulk must develop and implement written procedures, subject to the records requirements of § 1.912(a), adequate to ensure that a previous cargo does not make the food unsafe. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a).

(5) The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures, subject to the records requirements of § 1.912(a), to ensure that the food is transported under adequate temperature control. Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement subject to the records requirements of § 1.912(a) and must include measures equivalent to those specified for carriers under paragraphs (e)(1) through (3) of this section.

(c) *Requirements applicable to loaders engaged in transportation operations.* (1) Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment the loader must determine, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(1) of this section, that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, *e.g.,* it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.

(2) Before loading food that requires temperature control for safety, the loader must verify, considering, as appropriate, specifications provided by the shipper in accordance with paragraph (b)(2) of this section, that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation.

(d) *Requirements applicable to receivers engaged in transportation operations.* Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, *e.g.,* for off-odors.

(e) *Requirements applicable to carriers engaged in transportation operations.* When the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation, the carrier is responsible for the following functions as applicable per the agreement:

(1) A carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

(2) A carrier must, once the transportation operation is complete and if requested by the receiver, provide the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified by the shipper in accordance with paragraph (b)(2) of this section. Such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.

(3) Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety under the conditions of the shipment during transportation, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper in accordance with paragraph (b)(2) of this section.

(4) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that identifies the previous cargo transported in the vehicle.

(5) If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle.

(6) A carrier must develop and implement written procedures subject to the records requirements of § 1.912(b) that:

(i) Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required by § 1.906(b);

(ii) Describe how it will comply with the provisions for temperature control in paragraph (e)(2) of this section, and;

(iii) Describe how it will comply with the provisions for the use of bulk vehicles in paragraphs (e)(4) and (5) of this section.

Training

§ 1.910 What training requirements apply to carriers engaged in transportation operations?

(a) When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter.

(b) Carriers must establish and maintain records documenting the training described in paragraph (a) of this section. Such records must include the date of the training, the type of training, and the person(s) trained. These records are subject to the records requirements of § 1.912(c).

Records

§ 1.912 What record retention and other records requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations?

(a) Shippers must retain records:

(1) That demonstrate that they provide specifications and operating temperatures to carriers as required by § 1.908(b)(1) and (2) as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.

(2) Of written agreements and the written procedures required by § 1.908(b)(3), (4), and (5), for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(b) Carriers must retain records of the written procedures required by § 1.908(e)(6) for a period of 12 months beyond when the agreements and procedures are in use in their transportation operations.

(c) Carriers must retain training records required by § 1.910(b) for a period of 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided.

(d) Any person subject to this subpart must retain any other written agreements assigning tasks in compliance with this subpart for a period of 12 months beyond the termination of the agreements.

(e) Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity in accordance with the provisions of § 1.908(a)(5), must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.

(f) Shippers, receivers, loaders, and carriers must make all records required by this subpart available to a duly authorized individual promptly upon oral or written request.

(g) All records required by this subpart must be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

(h) Records that are established or maintained to satisfy the requirements of this subpart and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

(i) Except for the written procedures required by § 1.908(e)(6)(i), offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The written procedures required by § 1.908(e)(6)(i) must remain onsite as long as the procedures are in use in transportation operations. Electronic records are considered to be onsite if they are accessible from an onsite location.

(j) All records required by this subpart are subject to the disclosure requirements under part 20 of this chapter.

Waivers

§ 1.914 Under what circumstances will we waive a requirement of this subpart?

We will waive any requirement of this subpart with respect to any class of persons, vehicles, food, or nonfood products, when we determine that:

(a) The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and

(b) The waiver will not be contrary to the public interest.

§ 1.916 When will we consider whether to waive a requirement of this subpart?

We will consider whether to waive a requirement of this subpart on our own initiative or on the petition submitted under § 10.30 of this chapter by any person who is subject to the requirements of this subpart with respect to any class of persons, vehicles, food, or nonfood products.

§ 1.918 What must be included in the Statement of Grounds in a petition requesting a waiver?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a waiver must:

(a) Describe with particularity the waiver requested, including the persons, vehicles, food, or nonfood product(s) to which the waiver would apply and the requirement(s) of this subpart to which the waiver would apply; and

(b) Present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to the public interest.

§ 1.920 What information submitted in a petition requesting a waiver or submitted in comments on such a petition is publicly available?

We will presume that information submitted in a petition requesting a waiver and comments submitted on such a petition does not contain information exempt from public disclosure under part 20 of this chapter and would be made public as part of the docket associated with this request.

§ 1.922 Who will respond to a petition requesting a waiver?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN) or the Center for Veterinary Medicine (CVM), or the Director, Office of Compliance, CFSAN, or the Director, Office of Surveillance and Compliance, CVM, will respond to a petition requesting a waiver.

§ 1.924 What process applies to a petition requesting a waiver?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a waiver.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the waiver if the petition were to be granted.

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing.

(1) If we grant the petition, either in whole or in part, we will publish a notice in the **Federal Register** setting forth any waiver and the reasons for such waiver.

(2) If we deny the petition (including partial denials), our written response to the petitioner will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting waivers, including the status of each petition (for example, pending, granted, or denied).

§ 1.926 Under what circumstances may we deny a petition requesting a waiver?

We may deny a petition requesting a waiver if the petition does not provide the information required under § 1.918 (including the requirements of § 10.30 of this chapter), or if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health, or that the waiver could be contrary to the public interest.

§ 1.928 What process will we follow when waiving a requirement of this subpart on our own initiative?

If we, on our own initiative, determine that a waiver is appropriate, we will publish a notice in the **Federal Register** setting forth the waiver and the reasons for such waiver.

§ 1.930 When will a waiver that we grant become effective?

Any waiver that we grant will become effective on the date that notice of the waiver is published in the **Federal Register**.

§ 1.932 Under what circumstances may we modify or revoke a waiver?

We may modify or revoke a waiver if we determine that the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that the waiver could be contrary to the public interest.

§ 1.934 What procedures apply if we determine that a waiver should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify the entity that initially requested the waiver, in writing at the address identified in its petition, if we determine that a waiver granted in response to its petition should be modified or revoked.

(2) We will publish a notice of our determination that a waiver should be modified or revoked in the **Federal Register**. This notice will establish a public docket so that interested parties may submit written submissions on our determination.

(b) We will consider timely written submissions submitted to the public docket from interested parties.

(c) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (n) to read as follows:

§ 11.1 Scope.

* * * * *

(n) This part does not apply to records required to be established or maintained by subpart O of part 1 of this chapter. Records that satisfy the requirements of subpart O of part 1 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: March 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07330 Filed 4–5–16; 8:45 am]

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Part IV

Environmental Protection Agency

40 CFR Parts 60 and 63
National Emission Standards for Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units; Technical Correction; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[EPA–HQ–OAR–2009–0234 and EPA–HQ–OAR–2011–0044; FRL–9942–28–OAR]

RIN 2060–AS41

National Emission Standards for Hazardous Air Pollutants From Coal- and Oil-Fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units; Technical Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical corrections.

SUMMARY: This action finalizes the technical corrections that the Environmental Protection Agency (EPA) proposed on February 17, 2015, to correct and clarify certain text of the EPA's regulations regarding "National Emission Standards for Hazardous Air Pollutants from Coal- and Oil-fired Electric Utility Steam Generating Units and Standards of Performance for Fossil-Fuel-Fired Electric Utility, Industrial-Commercial-Institutional, and Small Industrial-Commercial-Institutional Steam Generating Units". We are also taking final action to remove the rule provision establishing an affirmative defense for malfunction.

DATES: The effective date of this rule is April 6, 2016.

ADDRESSES: *Docket.* The EPA has established two dockets for this action: Docket ID No. EPA–HQ–OAR–2011–0044 (new source performance standards (NSPS) action) and Docket ID No. EPA–HQ–OAR–2009–0234 (Mercury and Air Toxics Standards (MATS) action). All documents in the dockets are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available (*e.g.,* confidential business information or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Room 3334, EPA WJC West Building, 1301 Constitution Avenue NW., Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions about the MATS action: Mr. Jim Eddinger, Energy Strategies Group, Sector Policies and Programs Division (D243–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5426; fax number (919) 541–5450; email address: *eddinger.jim@epa.gov.* For questions about the NSPS action: Mr. Christian Fellner, Energy Strategies Group, Sector Policies and Programs Division (D243–01), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4003; fax number (919) 541–5450; email address: *fellner.christian@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. How can I get copies of this document and other related information?

This **Federal Register** document and the document titled "Summary of Public Comments and Responses: MATS and Utility NSPS Technical Corrections" (TC RTC) are available in the dockets the EPA established under Docket ID No. EPA–HQ–OAR–2009–0234 and Docket ID No. EPA–HQ–OAR–2011–0044. The TC RTC is available in both the MATS and Utility NSPS dockets by conducting a search of the title "Summary of Public Comments and Responses: MATS and Utility NSPS Technical Corrections." In addition to being available in the docket, electronic copies of these documents are available on the *www.regulations.gov* Web site. This **Federal Register** document and the TC RTC can also be found on the EPA's Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/atw/utility/utilitypg.html.*

B. Judicial Review

Under CAA section 307(b)(1), judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by June 6, 2016. Under CAA section 307(d)(7)(B), only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Note, under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce these requirements.

I. Background

The final Clean Air Act (CAA) rules published in the **Federal Register** on February 16, 2012 (77 FR 9303), establish national emission standards for hazardous air pollutants (NESHAP) from coal- and oil-fired electric utility steam generating units (EGUs), referred to as "MATS," and NSPS for fossil-fuel-fired electric utility, industrial-commercial-institutional, and small industrial-commercial-institutional steam generating units, referred to as the "Utility NSPS".

In the February 17, 2015, **Federal Register** (80 FR 8442), the EPA proposed to correct certain regulatory text. The proposed corrections were categorized generally as follows: (a) Resolution of conflicts between preamble and regulatory text, (b) corrections that were inadvertently not made that the EPA stated it would make in response to comments, and (c) clarification of language in regulatory text. In the proposed rule, the EPA identified each proposed technical correction to the regulatory text as found in the Code of Federal Regulations (*i.e.,* 40 CFR). Table 1 of this preamble lists the proposed revisions to the regulatory text that the EPA is finalizing. In Table 2 below, the EPA lists additional changes that the Agency determined were necessary to conform to changes the Agency included in the proposed rule.

TABLE 1—SUMMARY OF PROPOSED TECHNICAL CORRECTIONS AND CLARIFICATIONS BEING FINALIZED

Section of subpart Da (40 CFR part 60)	Description of correction (40 CFR part 60)
40 CFR 60.48Da(f)	Revise procedures for calculating compliance with the NSPS daily average particulate matter (PM) emission limit using PM continuous emission monitoring system (CEMS).
Section of subpart UUUUU (40 CFR part 63)	Description of correction (40 CFR part 63)
40 CFR 63.9983(a)	Revise to clarify that MATS does not apply to either major or area source combustion turbines, except for integrated gasification combined cycle (IGCC) units.
40 CFR 63.9983(b) and (c)	Revise consistent with the definitional changes in 40 CFR 63.10042.
40 CFR 63.9983(e)	Add to clarify applicability to units meeting the definition of a natural gas-fired EGU in MATS, and, because they combust greater than 10 percent biomass, also meet the definition of a biomass-fired boiler in the Industrial Boiler NESHAP (subpart DDDDD).
40 CFR 63.9991(c)(1) and (2)	Revise to clarify the conditions that are required in order to use the alternate sulfur dioxide (SO_2) limit.
40 CFR 63.10000(c)(1)(i)(A) and 63.10005(h) ...	Revise to clarify the provisions of units designated as being low emitting EGUs (LEE) when an acid gas scrubber and a bypass stack are present.
40 CFR 63.10000(c)(1)(i)(C)	Add to allow EGUs the ability to seek LEE status if their bypass stacks that are able to measure emissions and to allow EGUs with LEE status the ability to bypass emissions control devices during emergency periods.
40 CFR 63.10000(c)(2)(iii)	Revise to state that EGU choosing to use quarterly testing and parametric monitoring for hydrogen fluoride (HF) or hydrogen chloride (HCl) compliance must include the continuous monitoring systems (CMS) in their site-specific monitoring plans.
40 CFR 63.10000(m)	Add to clarify that EGUs choosing to meet the work practice standards contained in paragraph (2) of the definition of startup may verify, instead of certify, monitoring systems used to meet the work practice standards.
40 CFR 63.10001	Revise to remove the affirmative defense provisions.
40 CFR 63.10005(a)	Revise to clarify that different compliance demonstrations may require different and additional types of data collection and to clarify the date by which compliance must be demonstrated for existing EGUs.
40 CFR 63.10005(a)(2)	Revise to clarify the date by which compliance must be demonstrated for EGUs using CMS or sorbent trap monitoring systems.
40 CFR 63.10005(a)(2)(i)	Revise to clarify applicability of the provision to both the 30- and 90-boiler operating day performance testing requirements.
40 CFR 63.10005(b)(6)	Add to clarify the date EGUs must begin conducting required stack tests when stack test data collected prior to the applicable compliance date are submitted to satisfy initial performance test.
40 CFR 63.10005(d)(3) and (d)(4)(i)	Revise to more clearly state when compliance must be demonstrated.
40 CFR 63.10005(f)	Revise to clarify when sources must complete the initial tune-up after the compliance date, and the timing for subsequent tune-ups when the initial tune-up is conducted prior to the compliance date.
40 CFR 63.10005(h)(3)	Revise to clarify that the alternate 30- and 90-day averaging provisions are both applicable to mercury (Hg) emission limits.
40 CFR 63.10005(i)(4)	Revise to delete paragraphs (iii) and (iv). The identified test methods are not for determining fuel moisture content, as required in the provision.
40 CFR 63.10006(f)	Revise to specify EGU operational status with respect to performance testing; the requirements if the performance testing schedule is missed; and intervals between performance tests.
40 CFR 63.10009(a)(2) and (a)(2)(i)	Revise to clarify that the 90-boiler operating day averaging period is an option for Hg emissions from non-low rank virgin coal-fired EGUs.
40 CFR 63.10009(b)(1)	Revise to clarify group eligibility equations 1a and 1b.
40 CFR 63.10009(b)(2), (b)(3), (f)(2), (g)(1), (g)(2), and (j)(1)(ii).	Revise to correct the term "gross electric output" to "gross output" which is the term defined in 40 CFR 63.10042.
40 CFR 63.10009(f)	Revise to clarify the conditions for determining the ability of the emissions averaging group to meet the emissions limit and to clarify use of the alternate Hg emission limit.
40 CFR 63.10010(a)(4)	Revise to add requirement to route exhaust gases that bypass emissions control devices through stacks that contain monitoring so that emissions can be measured and to clarify that hours that a bypass stack is in use are to be counted as hours of deviation from monitoring requirements.
40 CFR 63.10010(f)(3)	Revise to clarify that 30-boiler operating day rolling averages are based only on valid hourly SO_2 emission rates.
40 CFR 63.10010(h)(6)(i) and (ii), (i)(5)(i)(A) and (B), and (j)(4)(i)(A) and (B).	Revise to clarify that data collected during certain periods are not to be included in compliance assessments but such periods are to be included in annual deviation reports.
40 CFR 63.10010(j)(l)(i)	Revise to replace the incorrect reference to § 63.7(e) with the correct reference to § 63.8(d)(2).
40 CFR 63.10010(l) and (l)(4)	Revise to clarify that EGU owners or operators who choose to meet the work practice standards contained in paragraph (2) of the definition of startup may verify, instead of certify, monitoring systems used.
40 CFR 63.10011(b)	Revise to remove the incorrect reference to Table 4 and to replace the incorrect reference to Table 7 with the correct reference to Table 6.

TABLE 1—SUMMARY OF PROPOSED TECHNICAL CORRECTIONS AND CLARIFICATIONS BEING FINALIZED—Continued

Section of subpart UUUUU (40 CFR part 63)	Description of correction (40 CFR part 63)
40 CFR 63.10011(c)(1) and (2)	Revise to clarify the date by which compliance must be demonstrated by EGUs that use CEMS or sorbent trap monitoring systems and to clarify in 40 CFR 63.10011(c)(1) that the alternate Hg emission limit may be used.
40 CFR 63.10011(e)	Revise to replace "according to" with "in accordance with."
40 CFR 63.10011(g)(4)(v)(A) and Table 3	Revise to clarify our intent by changing "to the maximum extent possible" to "to the maximum extent possible, taking into account boiler or control device integrity."
40 CFR 63.10020(e)	Revise to clarify that it applies only to EGU owners or operators who choose to meet the work practice standards contained in paragraph (2) of the definition of startup. In addition, the undefined term "electrical load" has been replaced with the defined term "gross output" and the incorrect terms "liquid to fuel ratio" and "the differential pressure of the liquid" have been replaced with the correct terms "liquid to flue gas ratio" and "the pressure drop across the scrubber."
40 CFR 63.10021(d)(3)	Revise to clarify the type of monitoring that is to be used to demonstrate compliance.
40 CFR 63.10021(e)	Revise to clarify the condition that allows delay of burner inspections for initial tune-ups.
40 CFR 63.10021(e)(9)	Revise to clarify the dates that tune-ups must be reported.
40 CFR 63.10023(b) and Table 6	Revise to clarify that all EGUs using PM continuous parametric monitoring systems (CPMS) for compliance purposes are to follow the same procedure for determining the operating limit.
40 CFR 63.10030(e)(1)	Revise to replace the phrase "identification of which subcategory the source is in" with "identification of the subcategory of the source."
40 CFR 63.10030(e)(7)(i)	Revise to delete and reserve since subsequent performance tests are not part of the Notification of Compliance Status.
40 CFR 63.10030(e)(7)(iii)	Add to establish the procedures by which an EGU owner or operator may switch between mass per heat input and mass per gross output emission limits.
40 CFR 63.10030(e)(8)(i)	Revise to clarify that it applies only to EGU owners or operators who choose to meet the work practice standards contained in paragraph (2) of the definition of startup. Revise to clarify that PM control device efficiencies and PM emission rates are those of periods other than startup and shutdown periods.
40 CFR 63.10030(e)(8)(ii)	Revise to remove the requirement for use of an independent professional engineer.
40 CFR 63.10030(f)	Revise to add notification requirements for EGUs that move in and out of MATS applicability.
40 CFR 63.10031(c)(4)	Revise to clarify the reporting requirements for EGU tune-ups.
40 CFR 63.10031(c)(5)	Revise to clarify that it applies only to EGU owners or operators who choose to meet the work practice standards contained in paragraph (2) of the definition of startup.
40 CFR 63.10031(c)(6)	Revise to add emergency bypass reporting for EGUs with LEE status.
40 CFR 63.10032(f)	Revise to clarify that the requirements of § 63.10032(f)(1) apply only to those EGU owners or operators who choose to meet the work practice standards contained in paragraph (1) of the definition of startup, while the requirements of § 63.10032(f)(2) apply only to those EGU owners or operators who choose to meet the work practice standards contained in paragraph (2) of the definition of startup.
40 CFR 63.10042	The definitions of "Coal-fired electric utility steam generating unit," "Coal refuse," "Fossil fuel-fired," "Integrated gasification combined cycle electric utility steam generating unit or IGCC," "Limited-use liquid oil-fired subcategory," "Natural gas-fired electric utility steam generating unit," and "Oil-fired electric utility steam generating unit" are revised to clarify the period of time to be included in determining the source's applicability to the MATS. A definition of "neural network" is added because the term is used in 40 CFR 63.10005(f), 63.10006(i), and 63.10021(e) and Table 3 to subpart UUUUU of Part 63 but is not defined.
Table 1 to subpart UUUUU of part 63	Revise to correct the term "gross electric output" to "gross output" which is the term defined in 40 CFR 63.10042.
Table 2 to subpart UUUUU of part 63	Revise to correct the term "gross electric output" to "gross output" which is the term defined in 40 CFR 63.10042. Provision 1(c) (the Hg limit for EGUs in the subcategory "unit designed for coal ≥8,300 Btu/lb") is also revised to clarify the applicability of the alternate 90-boiler operating day compliance option.
Table 3 to subpart UUUUU of part 63	Revise as described earlier to clarify the term "maximum extent possible.".
Table 4 to subpart UUUUU of part 63	Revise to clarify that existing as well as new EGUs using PM CPMS share the same procedures for developing operating limits.
Table 5 to subpart UUUUU of part 63	Revise to clarify that when using Method 29, the metals matrix spike and recovery levels are to be reported.
Table 6 to subpart UUUUU of part 63	Revise to clarify that existing, as well as new, EGUs using PM CPMS share the same procedures for developing operating limits.
Table 8 to subpart UUUUU of part 63	Revise to clarify that compliance reports are to include information required by 40 CFR 63.10031(c)(5) and (6).
Table 9 to subpart UUUUU of part 63	Revise to correct an inadvertent omission of 30-day notification requirements of 40 CFR 63.9.
Paragraphs 4.1.1.3 and 5.1.2.3 and Tables A–1 and A–2 to appendix A.	Revise to adjust Hg CEMS language regarding converters.
Paragraph 7.1.2.5 to appendix A	Add to require that owners or operators flag EGUs that are part of emission averaging groups.
Paragraph 3.2.1.2.1 of appendix A	Revise to specifically indicate that Hg gas generators and cylinders are allowed.
Paragraphs 4.1.1.1, Table A–1, Table A–2, 5.1.2.1, and 4.1.1.3 of appendix A.	Revise to exclude use of oxidized Hg gas standards for daily calibration of Hg CEMS.
Paragraph 5.1.2.3 of appendix A	Revise to make the weekly single level system integrity check mandatory.

TABLE 1—SUMMARY OF PROPOSED TECHNICAL CORRECTIONS AND CLARIFICATIONS BEING FINALIZED—Continued

Section of subpart UUUUU (40 CFR part 63)	Description of correction (40 CFR part 63)
Paragraphs 4.1.1.5.2, Table A–1, Table A–2, and 4.1.1.5 of appendix A.	Revise to provide an alternative relative accuracy test audit (RATA) procedure for EGUs with low emissions.
Paragraph 5.2.1 of appendix A	Revise to correct the number of days for sorbent trap use from 14 to 15.
Paragraph 6.2.2.3 of appendix A	Revise to clarify that the 90-day alternative Hg standard may be used and that electrical output is gross output.
Paragraph 7.1.2.6 of appendix A	Add to clarify that EGU owners or operators are to keep records of their EGUs that constitute emissions averaging groups.
Paragraphs 2.1, 2.3, 2.3.1, 2.3.2, 3.1, 3.2, 3.3, 5, 5.1, 5.2, and 5.3 of appendix B.	Revise to clarify that use of Performance Specification (PS) 18, when promulgated, will be allowed.
Paragraph 5.4 of appendix B	Add as part of the renumbering due to the addition of PS 18.
Paragraph 8 of appendix B	Revise to accommodate use of PS 18.
Paragraphs 10.1.8, 10.1.8.1, 10.1.8.1.1, and 10.1.8.1.2 of appendix B.	Revise as part of the renumbering due to the addition of PS 18.
Paragraph 10.1.8.1.3 of appendix B	Revise to clarify that records of relative accuracy audits (RAAs) are also required.
Paragraphs 10.1.8.2, 10.1.8.1.2.1, and 10.1.8.1.2.2 of appendix B.	Revise to clarify the quarterly gas audit recordkeeping requirements for PS 15 and the quarterly data accuracy assessments for PS 18 (which are reserved).
Paragraph 11.4 of appendix B	Revise to replace the incorrect abbreviation "*i.e.*" with "*e.g.*".
Paragraph 11.4.2 of appendix B	Revise to specify the requirements of the daily beam intensity checks for EGUs using PS 18.
Paragraph 11.4.3 of Appendix B	Revise to reflect the reporting requirements for PS 15.
Paragraph 11.4.4 of appendix B	Revise to reserve the reporting requirements for quarterly parameter verification checks for PS 18.
Paragraphs 11.4.4.1, 11.4.5, 11.4.5.1, 11.4.6, 11.4.6.1 of appendix B.	Add to reserve the reporting requirements for quarterly gas audit information and for quarterly dynamic spiking for PS 18.
Paragraph 11.4.7 of appendix B	Add to include reporting requirements for RAAs.
Paragraphs 11.4.7.1 through 11.4.7.13 of appendix B.	Add as part of the renumbering due to the addition of PS 18.
Paragraph 11.5.3.4 of appendix B	Revise to include reporting requirements for beam intensity checks for PS 18.

Most of the corrections and clarifications remain the same as presented in the proposed correction document and those changes are being finalized without further discussion. However, the EPA has made some changes in this final rule after consideration of the public comments received on the proposed correction document. The changes are to clarify applicability and implementation issues associated with proposed changes, and the significant changes are discussed below in this preamble. A summary of the comments received and our responses thereto is contained in the document "Summary of Public Comments and Responses: MATS and Utility NSPS Technical Corrections" located in the dockets for these rulemakings.

II. Significant Changes Since Proposal

This section of the preamble summarizes the significant changes made to the proposed corrections and clarifications.

1. Section 63.9984(f) is revised to add "or the EGU's otherwise applicable compliance date established by the EPA or the state." A commenter stated that the EPA's proposed revision, which was adding "the date that compliance must be demonstrated, as given" in § 63.9984, to the initial compliance requirements in § 63.10005(a) for existing EGUs, does not effectively clarify the date that compliance must be demonstrated due to its reference to § 63.9984 and paragraph (f) of § 63.9984 because § 63.9984(b) specifies a compliance date of April 16, 2015 for existing EGUs. Also, § 63.9984(f), which states the dates by which compliance must be demonstrated, refers to § 63.9984(b). Therefore, we revised § 63.9984(f) because specifying a date for existing EGUs to demonstrate compliance is confusing for existing sources that have been granted a compliance extension.

2. Section 63.10000(n) is added to address comments that noted the proposed technical corrections did not address the permanent conversion to natural gas or biomass consistent with the proposals outlined in the February 17, 2015 preamble. In the preamble (see 80 FR 8447), we stated "The EPA is also proposing that sources that permanently convert to natural gas or biomass after the compliance date are no longer subject to MATS, notwithstanding the coal or oil usage the previous 3 calendar years." However, we inadvertently did not include the necessary language to address permanent conversions in the proposed regulatory text. For that reason, we are revising paragraph (n) to incorporate the proposed change as outlined in the preamble to the proposed rule.

3. The proposal to revise § 63.10005(b)(1) to change the time period allowed for existing EGUs to use stack test data collected prior to the applicable compliance date has been withdrawn. Several commenters did not support the proposed revision to change the window in which initial compliance can be demonstrated, and said that EGUs should be allowed to demonstrate initial compliance using stack tests conducted on or after April 16, 2014. Commenters said the EPA's proposed change is unfair, renders investments in stack testing useless, and requires companies to perform new, unnecessary initial compliance testing. For these reasons, and because the Agency believes earlier stack tests may be representative under certain circumstances, the EPA is not making the proposed change.

4. Section 63.10006(f) is revised to: (1) Correct the minimum time between annual performance tests (from 370 to 320 calendar days); (2) clarify the minimum time between annual sorbent trap mercury testing for 30-boiler operating day low emitting EGU (LEE) retests (also 320 calendar days); and (3) provide the minimum time between annual sorbent trap mercury testing for 90-boiler operating day LEE retests (230 calendar days). Commenters correctly stated that the 370-day interval for annual tests was a typographical error, as they would expect the interval to be 365 days or less. Commenters expressed concerns that, while the proposed revised § 63.10006(f) specified the time

periods between annual performance tests, it did not specify the time periods between annual sorbent trap mercury testing for either the 30-boiler operating day averaging periods or the 90-boiler operating day averaging periods. The three revisions, listed above, being made to § 63.10006(f) address the commenters' concerns. In addition, § 63.10010(i)(2)(i) and (ii) is revised to clarify the time periods between quarterly, annual, and three year testing for particulate matter continuous emissions monitoring system (PM CEMS) audits.

5. Section 63.10009(b)(1) is revised to clarify group eligibility equations 1a and 1b. The purpose of the group eligibility equations is to provide EGU owners or operators a quick method for demonstrating initial compliance with the emission limits for all units participating in the emission averaging group using the maximum rated heat input or gross output of each unit and the results of the initial compliance demonstrations. Commenters stated that the EPA proposed to drop the double summation in the denominator, which is a correct step. However, the commenters indicated they do not understand what the Agency was thinking with respect to adding the "q_j" term in both the numerator and denominator and that the EPA defined "q_j" to be the hours in the averaging period (720 for 30-day averages and 2,160 for 90-day averages) because the term's presence in both the numerator and denominator cancels out and has no effect. Commenters also stated that they do not agree that the newly proposed group averaging eligibility Equation 1a is more useful than the original equation. Commenters said both the original equation and the newly proposed equation are flawed and, thus, produce incorrect results. Commenters said corrections need to be made to either equation that the EPA wants to use. Commenters said the stack testing components of the equation for each unit that is tested need to be weighted the same as units that use continuous monitoring in order for any equation to produce correct calculations. Commenters said the original equation works for the continuous monitoring components, but is flawed because it does not properly weight the stack testing components, and the newly proposed equation is flawed on both fronts. Based on the commenters' concerns, the equations have been revised so that individual EGU characteristics, whether from continuous emission monitoring systems (CEMS) or stack testing results, are easier to input. We agree that the added "q_j" term and "r_k" term have no effect, and they have been deleted. We are also deleting the "n" term since Equations 1a and 1b are to demonstrate initial compliance based on using the initial compliance results and not continuous compliance that is based on an averaging period. We have revised some of the terms' descriptions to clarify that the emission rates used are those determined during the initial compliance demonstration.

6. Section 63.10009(e), (g), and (j)(2) are revised to require compliance with the weighted average emissions rate at all times following the date that emissions averaging begins. A commenter argued that the EPA must also revise these sections to remove the specifically identified dates (*e.g.,* April 16, 2015 and February 16, 2015). We agree that the dates within § 63.10009(e), (g), and (j)(2) should be removed, and the dates have been replaced with "the date that you begin emission averaging."

7. Section 63.10010(h)(6)(i), (i)(5)(i)(A), and (j)(4)(i)(A) and (B) are revised to clarify when monitoring system quality assurance or quality control activities are to be reported. Commenters said § 63.10010(h)(6)(i), (i)(5)(i)(A), and (j)(4)(i)(A) and (B) specify what data from particulate matter (PM) continuous parameter monitoring system (CPMS), PM CEMS, and hazardous air pollutants (HAP) metal CEMS must be excluded from compliance determinations and that the EPA proposed to separate the language regarding deviation reporting that currently appears at the end of these provisions into a separate sentence to "ease readability." The commenter disagreed that the proposed revision improves readability and said that, to the contrary, by separating out the sentence, the EPA implies that the periods when data are not collected because of monitoring system malfunctions, repairs, required quality assurance or quality control, as well as periods when a monitoring system is out of control, are deviations from monitoring requirements, which they are not. The commenter is incorrectly interpreting the proposed change. Periods when data are not collected because of monitoring system malfunctions are deviations. The required quality assurance or quality control activities that are deviations from monitoring requirements are, as stated in § 63.10010(h)(6)(i), (i)(5)(i)(A), and (j)(4)(i)(A) and (B), those conducted during monitoring systems malfunctions.

8. Section 63.10011(g)(4)(v)(A) is revised to change the proposed language "to the maximum extent practicable" back to the language "to the maximum extent possible" as in the final rule. Commenters said the requirement to use clean fuels "to the maximum extent practicable" does not even address the level of toxic emissions during startup, let alone reduce them to the maximum extent achievable as is required under CAA section 112(d)(2). Commenters said, perhaps most importantly, that the EPA's proposed change impermissibly assumes that existing older boilers and control devices are not capable of being upgraded—despite Congress' mandate in CAA section 112(d)(2)–(3) that emissions standards and work practices reflect what is achievable and actually being achieved by the best-performing sources. Commenters said further, under CAA section 112(d), it is the Administrator's duty to establish standards to achieve the required emissions reductions—not the duty of owners and operators. Commenters said the EPA's purported work practices impermissibly allow operators themselves to determine the standards and their own emission reductions achieved (or not) by the requirements. Commenters said the EPA's proposed change leaves it up to each operator to determine the amount of clean fuel use that represents the "maximum extent practicable," and leaves it up to each operator to determine what qualifies as a "consideration such as boiler or control device integrity." Commenters said that even though the requirement for clean fuels states that EGUs must have sufficient clean fuel capacity to engage and operate PM control devices within 1 hour of adding the primary fuel (and even though a separate work practice requires PM controls to be engaged and operated within 1 hour), these requirements do not establish whether and to what point EGUs must actually use clean fuels in startups. These comments primarily concern issues that the EPA did not reopen in the proposed document. Because those issues were not reopened, the EPA did not respond to these comments. We did propose to change § 63.10011(g)(4)(v)(A) as the commenter states. We continue to believe that the use of clean fuels during startup must be maximized to reduce HAP emissions and have reconsidered the proposed change of "possible" to "practicable." We believe "possible" is a more enforceable standard. The final change to § 63.10011(g)(4)(v)(A) is: "to the maximum extent possible, taking into account considerations such as boiler or control device integrity,

throughout the startup period." This language is also included in section 4 of Table 3, to clarify that this provision applies during periods of shutdown.

The EPA is not finalizing the proposed change because we have determined that requiring clean fuel use to the maximum extent "possible" is more enforceable than the proposed change to "practicable", and the Agency believes it is critical that the work practice be enforceable to ensure that sources use as much clean fuel with its inherently low HAP content as possible when a source's controls are not yet fully engaged. At the same time, we believe operators must be able to consider the integrity of the EGU system when determining the clean fuel use that is "possible" for a given unit. We believe the final rule addresses both considerations.

9. Section 63.10030(e)(8)(iii) is added to allow EGU owners or operators the ability to switch between paragraphs 1 and 2 of the startup definition. Commenters requested that switching between paragraphs of the definition of startup not be prohibited. We have no objection to such switching provided certain criteria are met. Just as we had not considered that EGU owners or operators would want to switch between mass per year heat input emission limits and mass per gross output emission limits, but proposed to allow such changes provided certain criteria are met, we did not consider that an owner or operator would want to switch between the startup definitions for the EGU. Given the commenter's specific request and the EPA's conditional approval based on the already existing model given in § 63.10030(e)(7)(iii)(A), § 63.10030(e)(8)(iii) is added to the rule. This new section allows EGU owners or operators the ability to switch between paragraphs 1 and 2 of the startup definition provided, among other things, that the EGUs involved in the switch are identified, that a request is submitted 30 days prior to the anticipated switch, that the request contains certification that all previous plans, such as monitoring and emissions averaging, are revised, that records are maintained, and that the new definition is not used until the next reporting period after receipt of written acknowledgement from the Administrator or the delegated authority of the switch.

10. Section 63.10031(c)(4) is revised to clarify that the "date" of the tune-up is the date the tune-up provisions specified in § 63.10021(e)(6) and (7) are completed. Commenters noted that there will not necessarily be a single date associated with completion of an EGU's tune-ups conducted under § 63.10021(e) and suggested that, related to the possibility of a delayed burner inspection, the Agency make it clear that compliance with all requirements besides the burner inspection must occur by the compliance demonstration date, but that the burner inspection may be delayed, and to revise the provision to recognize that as a result, performance of subsequent inspections and tune-ups may be on a separate 36-month track and some EGUs may have "dates" rather than a "date" for completion of requirements. Regardless of when the burner inspection is conducted, the tune-up is considered to have been conducted on the date the combustion optimization is completed. The purpose of the tune-up is the optimization of the combustion to minimize organic HAP, carbon monoxide, and nitrogen oxides (NO_X) and to improve or return the unit to its design combustion efficiency (*i.e.,* § 63.10021(e)(6) and (7)). We realize that EGUs may need to be taken off-line to conduct an inspection of burners. So, we allow that inspection to be delayed, or as § 63.10021(e) is revised, to be performed prior to the tune-up. Therefore, subsequent tune-ups must be performed within 36 months from when the previous tune-up (*i.e.,* the requirements of § 63.10021(e)(6) and (7)) was completed, and the source must conduct the next burner inspection on a similar schedule.

11. Section 63.10031(c)(7) is added to include the reporting requirements that have been removed from § 63.10030(e)(7)(i). A commenter said that there is no reason to submit Notification of Compliance Status (NOCS) for ongoing 3-year tests that are performed to demonstrate that LEE status is maintained, so the proposed language in § 63.10030(e)(7)(i) should be revised. We agree that not only the ongoing 3-year LEE retests, but also the annual and quarterly LEE retests and annual retests that are performed to establish operating limits, should not be submitted as NOCS. According to the introductory text of § 63.10030(e), the NOCS is required only for reporting initial compliance. Therefore, § 63.10030(e)(7)(i) has been removed and reserved, and the reporting requirements in § 63.10030(e)(7)(i) have been moved to a new place, *i.e.,* § 63.10031(c)(7), and are part of the compliance report requirements. Likewise, the compliance certification and deviation information requirements in § 63.10030(e)(5) and (e)(6) apply for compliance reports and are replicated in new § 63.10031(c)(8) and (9), and each of these paragraphs is included in the introductory text in § 63.10030(c) and in Table 8.

12. The definitions of "Coal-fired electric utility steam generating unit," "Fossil fuel-fired," "Limited-use liquid oil-fired subcategory," and "Oil-fired electric utility steam generating unit" in § 63.10042 are further revised to clarify the period of time to be included in determining the source's applicability to the MATS.

One commenter indicated that the proposed rule does not address permanent conversion to natural gas or biomass, nor does it make clear that, after the first 3 years of compliance, EGUs are required to evaluate applicability based on coal or oil usage from the 3 previous calendars years on an annual rolling basis. The commenter said that the EPA's clarifying proposals are not clearly outlined in the proposed revised definitions. The commenter urged the EPA to revise the definition in a manner consistent with the proposals outlined in the preamble. Several commenters indicated the proposed changes do not prevent an EGU from continuing to be subject to MATS for several years after a fuel switch.

We agree that the proposed clarification to the definitions does not make it clear that, after the first 3 years of compliance, an EGU is required to evaluate applicability based on coal or oil usage from the 3 previous calendar years on an annual rolling basis. Thus, we have revised the definitions for "Coal-fired electric utility steam generating unit," "Oil-fired electric utility steam generating unit," and "Fossil fuel-fired" to clarify that applicability after the first 3 years of compliance will be based on coal or oil usage from the 3 previous calendar years on an annual rolling basis.

Concerning the permanent fuels switch, the EPA explained above that it has addressed permanent conversions in § 63.10000(n) of the final rule, as discussed in paragraph 2 above.

13. Appendix A is finalized with all proposed revisions with the exception of adding an alternative specification for the relative accuracy test audit (RATA) where commenters provided data to support a different approach using an absolute value criterion. However, due to the current lack of available NIST-traceable elemental Hg gas cylinders, owners or operators of EGUs that have purchased/installed Hg CEMS that lack integrated elemental Hg gas generators may continue to use NIST-traceable oxidized gases for calibration error tests and daily checks until such time that NIST-traceable compressed elemental Hg gas standards are available and traceable with a combined uncertainty

(K=2) of 5 percent. Once those standards are available, we will issue a notice of availability in the **Federal Register**. Should NIST-traceable oxidized mercury reference gases with a combined uncertainty of 5% ultimately be available, we will consider allowing their use for calibration error tests and checks.

14. Appendix B is finalized with all proposed revisions except those related to sections 10 and 11 regarding recordkeeping and reporting for hydrogen chloride (HCl) CEMS subject to PS 18. Sections 10 and 11 will be addressed in the upcoming MATS Completion of Electronic Reporting Requirements rule. One change has been made that was not proposed. A minor technical correction has been made to section 9.4, requiring the HCl emission rates to be reported to 2 significant figures in scientific notation, which is consistent with the way that the emission standards are presented in Tables 1 and 2.

III. Other Corrections and Clarifications

In finalizing the rule, the EPA is addressing several other technical corrections and clarifications in the regulatory language based on public comments that were received on the February 2015 proposal that the Agency determined were necessary to conform to changes included in the proposed rule, as outlined in Table 2 of this preamble.

TABLE 2—SUMMARY OF TECHNICAL CORRECTIONS AND CLARIFICATIONS SINCE FEBRUARY 17, 2015, PROPOSAL

Section of subpart UUUUU (40 CFR part 63)	Description of correction (40 CFR part 63)
40 CFR 63.10000(a)	Revise this paragraph by adding "items 3 and 4" to clarify which items in Table 3 must be met.
40 CFR 63.10000(f)	Revise this paragraph to add "Except as provided under paragraph (n) of this section" due to the addition of paragraph (n) clarifying the applicability of a permanent conversion to natural gas or biomass.
40 CFR 63.10000(g)	Revise this paragraph to add "Except as provided under paragraph (n) of this section" due to the addition of paragraph (n) clarifying the applicability of a permanent conversion to natural gas or biomass.
40 CFR 63.10000(i)(1)	Revise this paragraph to clarify that an EGU, no longer subject to MATS, must be in compliance with applicable CAA section 112 or 129 standards consistent with paragraphs (g) and (n).
40 CFR 63.10005(a)	Revise this paragraph to replace the terms "electrical" and "electrical load" with the terms "gross" and "gross output," respectively, to be consistent with the proposed changes to other sections.
40 CFR 63.10005(a)(2)(ii)	Revise this paragraph to replace the terms "electrical" and "electrical load" with the terms "gross" and "gross output," respectively, to be consistent with the proposed changes to other sections.
40 CFR 63.10005(b)(4)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
40 CFR 63.10005(f)	Revise to be consistent with EPA's intent, as explained in the preamble to the proposed rule, to only clarify the timing of initial and subsequent tune-ups. Revise since specifying the date is problematic for sources that have been granted a compliance extension.
40 CFR 63.10005(h)(3)(i)(D)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
40 CFR 63.10005(h)(3)(iii)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
40 CFR 63.10007(f)(2)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
40 CFR 63.10009(e) and (j)(2)	Revise since specifying the date is problematic for sources that have been granted a compliance extension.
40 CFR 63.10010(f)(4)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
40 CFR 63.10021(h)(1)	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.
Table 5	Revise this table to replace the term "electrical" with the term "gross" to be consistent with the proposed changes to other sections.
Paragraph 7.1.8.5 of appendix A	Revise this paragraph to replace the term "electrical load" with the term "gross output" to be consistent with the proposed changes to other sections.

IV. Affirmative Defense for Violation of Emission Standards During Malfunction

The EPA received numerous comments on the affirmative defense to civil penalties for violations caused by malfunctions that the EPA proposed to remove in the current rule. Several commenters supported the removal of the affirmative defense for malfunctions. Other commenters opposed the removal of the affirmative defense provision.

As stated in the February 17, 2015, proposal, the United States Court of Appeals for the District of Columbia Circuit vacated an affirmative defense in one of the EPA's CAA section 112(d) regulations. *NRDC* v. *EPA*, No. 10–1371 (D.C. Cir. April 18, 2014) 2014 U.S. App. LEXIS 7281 (vacating affirmative defense provisions in CAA section 112(d) rule establishing emission standards for Portland cement kilns). The court found that the EPA lacked authority to establish an affirmative defense for private civil suits and held that under the CAA, the authority to determine civil penalty amounts in such cases lies exclusively with the courts, not the EPA. Specifically, the court found: "As the language of the statute makes clear, the courts determine, on a case-by-case basis, whether civil penalties are 'appropriate.' " See *NRDC*, 2014 U.S. App. LEXIS 7281 at *21 ("[U]nder this statute, deciding whether penalties are 'appropriate' in a given private civil suit is a job for the courts, not EPA."). The EPA is finalizing the proposed removal of the regulatory affirmative defense provision from MATS. In the event that a source fails to comply with an applicable CAA section 112(d) standard as a result of a malfunction event, the EPA's ability to exercise its case-by-case-enforcement discretion to determine an appropriate response provides sufficient flexibility in such circumstances as was explained in the preamble to the proposed rule. Further, as the D.C. Circuit recognized, in an EPA or citizen enforcement action, the court has the discretion to consider any defense raised and determine whether penalties are appropriate. Cf. NRDC, 2014 U.S. App. LEXIS 7281 at *24 (arguments that violation were caused by unavoidable technology failure can be made to the courts in future civil cases when the issue arises). The same is true for the presiding officer in EPA administrative enforcement actions. For all these reasons, this final rule removes the affirmative defense provisions.

V. Impacts of This Final Rule

This action finalizes certain provisions and makes technical and clarifying corrections, but does not promulgate substantive changes to the February 2012 final MATS (77 FR 9304). Therefore, there are no environmental, energy, or economic impacts associated with this final action. The impacts associated with MATS are discussed in detail in the February 16, 2012, final MATS rule.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations (40 CFR part 63, subpart UUUUU) and has assigned OMB control number 2060–0567. This action is believed to result in no changes to the ICR of the February 2012 final MATS rule, so that the information collection estimate of project cost and hour burden from the final MATS have not been revised.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This action finalizes changes to MATS to correct and clarify implementation issues raised by stakeholders.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This rule promulgates amendments to the February 2012 final MATS, but the amendments are clarifications to existing rule language to aid in implementation. Therefore, the action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. This action clarifies certain components of the February 2012 final MATS. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards from those contained in the February 16, 2012, final rule. Therefore, the EPA did not consider the use of any voluntary consensus standards. *See* 77 FR 9441–9443 for the NTTAA discussion in the February 16, 2012, final rule.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will **not** have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations because it does not affect the level of protection provided to human health or the environment.

The environmental justice finding in the February 2012 final MATS remains relevant in this action, which finalizes changes to the rule to correct and clarify implementation issues raised by stakeholders.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: March 17, 2016.

Gina McCarthy,

Administrator.

For the reasons discussed in the preamble, the EPA amends 40 CFR parts 60 and 63 as follows:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Section 60.48Da is amended by revising paragraph (f) to read as follows:

§ 60.48Da Compliance provisions.

* * * * *

(f) For affected facilities for which construction, modification, or reconstruction commenced before May 4, 2011, compliance with the applicable daily average PM emissions limit is determined by calculating the arithmetic average of all hourly emission rates each boiler operating day, except for data obtained during startup, shutdown, or malfunction periods. Daily averages are only calculated for boiler operating days that have non-out-of-control data for at least 18 hours of unit operation during which the standard applies. Instead, all of the non-out-of-control hourly emission rates of the operating day(s) not meeting the minimum 18 hours non-out-of-control data daily average requirement are averaged with all of the non-out-of-control hourly emission rates of the next boiler operating day with 18 hours or more of non-out-of-control PM CEMS data to determine compliance. For affected facilities for which construction or reconstruction commenced after May 3, 2011 that elect to demonstrate compliance using PM CEMS, compliance with the applicable PM emissions limit in § 60.42Da is determined on a 30-boiler operating day rolling average basis by calculating the arithmetic average of all hourly PM emission rates for the 30 successive boiler operating days, except for data obtained during periods of startup and shutdown.

* * * * *

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 3. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 4. Section 63.9983 is amended by:

■ a. Revising the section heading and paragraphs (a), (b), and (c); and

■ b. Adding paragraph (e).

The revisions and addition read as follows:

§ 63.9983 Are any fossil fuel-fired electric generating units not subject to this subpart?

* * * * *

(a) Any unit designated as a major source stationary combustion turbine subject to subpart YYYY of this part and any unit designated as an area source stationary combustion turbine, other than an integrated gasification combined cycle (IGCC) unit.

(b) Any electric utility steam generating unit that is not a coal- or oil-fired EGU and that meets the definition of a natural gas-fired EGU in § 63.10042.

(c) Any electric utility steam generating unit that has the capability of combusting more than 25 MW of coal or oil but does not meet the definition of a coal- or oil-fired EGU because it did not fire sufficient coal or oil to satisfy the average annual heat input requirement set forth in the definitions for coal-fired and oil-fired EGUs in § 63.10042. Heat input means heat derived from combustion of fuel in an EGU and does not include the heat derived from preheated combustion air, recirculated flue gases or exhaust gases from other sources (such as stationary gas turbines, internal combustion engines, and industrial boilers).

* * * * *

(e) Any electric utility steam generating unit that meets the definition of a natural gas-fired EGU under this subpart and that fires at least 10 percent biomass is an industrial boiler subject to standards established under subpart DDDDD of this part, if it otherwise meets the applicability provisions in that rule.

■ 5. Section 63.9991 is amended by revising paragraphs (c)(1) and (2) to read as follows:

§ 63.9991 What emission limitations, work practice standards, and operating limits must I meet?

* * * * *

(c) * * *

(1) Has a system using wet or dry flue gas desulfurization technology and an SO_2 continuous emissions monitoring system (CEMS) installed on the EGU; and

(2) At all times, you operate the wet or dry flue gas desulfurization technology and the SO_2 CEMS installed on the EGU consistent with § 63.10000(b).

■ 6. Section 63.10000 is amended by revising paragraphs (a), (c)(1)(i), (c)(2)(iii), (f), (g), and (i)(1) and adding paragraphs (m) and (n) to read as follows:

§ 63.10000 What are my general requirements for complying with this subpart?

(a) You must be in compliance with the emission limits and operating limits in this subpart. These limits apply to you at all times except during periods of startup and shutdown; however, for coal-fired, liquid oil-fired, or solid oil-derived fuel-fired EGUs, you are required to meet the work practice requirements, items 3 and 4, in Table 3 to this subpart during periods of startup or shutdown.

* * * * *

(c)(1) * * *

(i) For a coal-fired or solid oil-derived fuel-fired EGU or IGCC EGU, you may conduct initial performance testing in accordance with § 63.10005(h), to determine whether the EGU qualifies as a low emitting EGU (LEE) for one or more applicable emission limits, except as otherwise provided in paragraphs (c)(1)(i)(A) and (B) of this section:

(A) Except as provided in paragraph (c)(1)(i)(C) of this section, you may not pursue the LEE option if your coal-fired, IGCC, or solid oil-derived fuel-fired EGU is equipped with a main stack and a bypass stack or bypass duct configuration that allows the effluent to bypass any pollutant control device.

(B) You may not pursue the LEE option for Hg if your coal-fired, solid oil-derived fuel-fired EGU or IGCC EGU is new.

(C) You may pursue the LEE option provided that:

(*1*) Your EGU's control device bypass emissions are measured in the bypass stack or duct or your control device bypass exhaust is routed through the EGU main stack so that emissions are measured during the bypass event; or

(*2*) Except for hours during which only clean fuel is combusted, you bypass your EGU control device only during emergency periods for no more than a total of 2 percent of your EGU's annual operating hours; you use clean fuels to the maximum extent possible during an emergency period; and you prepare and submit a report describing the emergency event, its cause, corrective action taken, and estimates of emissions released during the emergency event. You must include these emergency emissions along with performance test results in assessing whether your EGU maintains LEE status.

* * * * *

(2) * * *

(iii) If your existing liquid oil-fired unit does not qualify as a LEE for hydrogen chloride (HCl) or for hydrogen fluoride (HF), you may demonstrate initial and continuous compliance through use of an HCl CEMS, an HF CEMS, or an HCl and HF CEMS, installed and operated in accordance with Appendix B to this rule. As an alternative to HCl CEMS, HF CEMS, or HCl and HF CEMS, you may demonstrate initial and continuous compliance through quarterly performance testing and parametric monitoring for HCl and HF. If you choose to use quarterly testing and parametric monitoring, then you must also develop a site-specific monitoring plan that identifies the CMS you will use to ensure that the operations of the EGU remains consistent with those during the performance test. As another alternative, you may measure or obtain, and keep records of, fuel moisture content; as long as fuel moisture does not exceed 1.0 percent by weight, you need not conduct other HCl or HF monitoring or testing.

* * * * *

(f) Except as provided under paragraph (n) of this section, you are subject to the requirements of this subpart for at least 6 months following the last date you met the definition of an EGU subject to this subpart (*e.g.*, 6 months after a cogeneration unit provided more than one third of its potential electrical output capacity and more than 25 megawatts electrical output to any power distributions system for sale). You may opt to remain subject to the provisions of this subpart beyond 6 months after the last date you met the definition of an EGU subject to this subpart, unless your unit is a solid waste incineration unit subject to standards under CAA section 129 (*e.g.*, 40 CFR part 60, subpart CCCC (New Source Performance Standards (NSPS) for Commercial and Industrial Solid Waste Incineration Units, or subpart DDDD (Emissions Guidelines (EG) for Existing Commercial and Industrial Solid Waste Incineration Units). Notwithstanding the provisions of this subpart, an EGU that starts combusting solid waste is immediately subject to standards under CAA section 129 and the EGU remains subject to those standards until the EGU no longer meets the definition of a solid waste incineration unit consistent with the provisions of the applicable CAA section 129 standards.

(g) Except as provided under paragraph (n) of this section, if your unit no longer meets the definition of an EGU subject to this subpart you must be in compliance with any newly applicable standards on the date you are no longer subject to this subpart. The date you are no longer subject to this subpart is a date selected by you, that must be at least 6 months from the date that your unit last met the definition of an EGU subject to this subpart or the date you begin combusting solid waste, consistent with § 63.9983(d). Your source must remain in compliance with this subpart until the date you select to cease complying with this subpart or the date you begin combusting solid waste, whichever is earlier.

* * * * *

(i)(1) If you own or operate an EGU subject to this subpart and cease to operate in a manner that causes your unit to meet the definition of an EGU subject to this subpart, you must be in compliance with any newly applicable section 112 or 129 standards on the date you selected consistent with paragraphs (g) and (n) of this section.

* * * * *

(m) Should you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU, on or before the date your EGU is subject to this subpart, you must install, verify, operate, maintain, and quality assure each monitoring system necessary for demonstrating compliance with the work practice standards for PM or non-mercury HAP metals controls during startup periods and shutdown periods required to comply with § 63.10020(e).

(1) You may rely on monitoring system specifications or instructions or manufacturer's specifications when installing, verifying, operating, maintaining, and quality assuring each monitoring system.

(2) You must collect, record, report, and maintain data obtained from these monitoring systems during startup periods and shutdown periods.

(n) If you have permanently converted your EGU from coal or oil to natural gas or biomass after your compliance date (or, if applicable, after your approved extended compliance date), as demonstrated by being subject to a permit provision or physical limitation (including retirement) that prevents you from operating in a manner that would subject you to this subpart, you are no longer subject to this subpart, notwithstanding the coal or oil usage in the previous calendar years. The date on which you are no longer subject to this subpart is the date on which you converted to natural gas or biomass firing; it is also the date on which you must be in compliance with any newly applicable standards.

§ 63.10001 [Removed and Reserved]

■ 7. Section 63.10001 is removed and reserved.

■ 8. Section 63.10005 is amended by:

■ a. Revising paragraphs (a) introductory text, (a)(2) introductory text, (a)(2)(i) and (ii), and (b)(4);

■ b. Adding paragraph (b)(6);

■ c. Revising paragraphs (d)(3), (d)(4)(i), (f), (h) introductory text, (h)(3) introductory text, (h)(3)(i)(D), and (h)(3)(iii) introductory text; and

■ d. Removing paragraphs (i)(4)(iii) and (iv).

The revisions and additions read as follows:

§ 63.10005 What are my initial compliance requirements and by what date must I conduct them?

(a) *General requirements.* For each of your affected EGUs, you must demonstrate initial compliance with each applicable emissions limit in Table 1 or 2 of this subpart through performance testing. Where two emissions limits are specified for a particular pollutant (*e.g.*, a heat input-based limit in lb/MMBtu and a gross output-based limit in lb/MWh), you may demonstrate compliance with either emission limit. For a particular compliance demonstration, you may be required to conduct one or more of the following activities in conjunction with performance testing: collection of data, *e.g.*, hourly gross output data (megawatts); establishment of operating limits according to § 63.10011 and Tables 4 and 7 to this subpart; and CMS performance evaluations. In all cases, you must demonstrate initial compliance no later than the date in paragraph (f) of this section for tune-up work practices for existing EGUs; the date that compliance must be demonstrated, as given in § 63.9984 for other requirements for existing EGUs; and in paragraph (g) of this section for all requirements for new EGUs.

* * * * *

(2) To demonstrate initial compliance using either a CMS that measures HAP concentrations directly (*i.e.*, an Hg, HCl, or HF CEMS, or a sorbent trap monitoring system) or an SO_2 or PM CEMS, the initial performance test shall consist of 30- or, for certain coal-fired existing EGUs that use emissions averaging for Hg, 90-boiler operating days. If the CMS is certified prior to the compliance date (or, if applicable, the approved extended compliance date), the test shall begin with the first operating day on or after that date, except as otherwise provided in paragraph (b) of this section. If the CMS is not certified prior to the compliance

date, the test shall begin with the first operating day after certification testing is successfully completed. In all cases, the initial 30- or 90- operating day averaging period must be completed on or before the date that compliance must be demonstrated (*i.e.,* 180 days after the applicable compliance date).

(i) The CMS performance test must demonstrate compliance with the applicable Hg, HCl, HF, PM, or SO_2 emissions limit in Table 1 or 2 to this subpart.

(ii) You must collect hourly data from auxiliary monitoring systems (*i.e.,* stack gas flow rate, CO_2, O_2, or moisture, as applicable) during the performance test period, in order to convert the pollutant concentrations to units of the standard. If you choose to comply with a gross output-based emission limit, you must also collect hourly gross output data during the performance test period.

* * * * *

(b) * * *

(4) A record of all parameters needed to convert pollutant concentrations to units of the emission standard (*e.g.,* stack flow rate, diluent gas concentrations, hourly gross outputs) is available for the entire performance test period; and

* * * * *

(6) For performance stack test data that are collected prior to the date that compliance must be demonstrated and are used to demonstrate initial compliance with applicable emissions limits, the interval for subsequent stack tests begins on the date that compliance must be demonstrated.

* * * * *

(d) * * *

(3) For affected EGUs that are either required to or elect to demonstrate initial compliance with the applicable Hg emission limit in Table 1 or 2 of this subpart using Hg CEMS or sorbent trap monitoring systems, initial compliance must be demonstrated no later than the applicable date specified in § 63.9984(f) for existing EGUs and in paragraph (g) of this section for new EGUs. Initial compliance is achieved if the arithmetic average of 30- (or 90-) boiler operating days of quality-assured CEMS (or sorbent trap monitoring system) data, expressed in units of the standard (see section 6.2 of appendix A to this subpart), meets the applicable Hg emission limit in Table 1 or 2 to this subpart.

(4) * * *

(i) You must demonstrate initial compliance no later than the applicable date specified in § 63.9984(f) for existing EGUs and in paragraph (g) of this section for new EGUs.

* * * * *

(f) For an existing EGU without a neural network, a tune-up, following the procedures in § 63.10021(e), must occur within 6 months (180 days) after April 16, 2015. For an existing EGU with a neural network, a tune-up must occur within 18 months (545 days) after April 16, 2016. If a tune-up occurs prior to April 16, 2015, you must keep records showing that the tune-up met all rule requirements.

* * * * *

(h) *Low emitting EGUs.* The provisions of this paragraph (h) apply to pollutants with emissions limits from new EGUs except Hg and to all pollutants with emissions limits from existing EGUs. You may pursue this compliance option unless prohibited pursuant to § 63.10000(c)(1)(i).

* * * * *

(3) For Hg, you must conduct a 30- (or 90-) boiler operating day performance test using Method 30B in appendix A–8 to part 60 of this chapter to determine whether a unit qualifies for LEE status. Locate the Method 30B sampling probe tip at a point within 10 percent of the duct area centered about the duct's centroid at a location that meets Method 1 in appendix A–1 to part 60 of this chapter and conduct at least three nominally equal length test runs over the 30- (or 90-) boiler operating day test period. You may use a pair of sorbent traps to sample the stack gas for a period consistent with that given in section 5.2.1 of appendix A to this subpart. Collect Hg emissions data continuously over the entire test period (except when changing sorbent traps or performing required reference method QA procedures). As an alternative to constant rate sampling per Method 30B, you may use proportional sampling per section 8.2.2 of Performance Specification 12 B in appendix B to part 60 of this chapter.

(i) * * *

(D) Hourly gross output data (megawatts), from facility records.

* * * * *

(iii) Calculate the average Hg concentration, in $\mu g/m^3$ (dry basis), for the 30- (or 90-) boiler operating day performance test, as the arithmetic average of all Method 30B sorbent trap results. Also calculate, as applicable, the average values of CO_2 or O_2 concentration, stack gas flow rate, stack gas moisture content, and gross output for the test period. Then:

* * * * *

■ 9. Section 63.10006 is amended by revising paragraph (f) and removing paragraph (j) to read as follows:

§ 63.10006 When must I conduct subsequent performance tests or tune-ups?

* * * * *

(f) *Time between performance tests.* (1) Notwithstanding the provisions of § 63.10021(d)(1), the requirements listed in paragraphs (g) and (h) of this section, and the requirements of paragraph (f)(3) of this section, you must complete performance tests for your EGU as follows:

(i) At least 45 calendar days, measured from the test's end date, must separate performance tests conducted every quarter;

(ii) For annual testing:

(A) At least 320 calendar days, measured from the test's end date, must separate performance tests;

(B) At least 320 calendar days, measured from the test's end date, must separate annual sorbent trap mercury testing for 30-boiler operating day LEE tests;

(C) At least 230 calendar days, measured from the test's end date, must separate annual sorbent trap mercury testing for 90-boiler operating day LEE tests; and

(iii) At least 1,050 calendar days, measured from the test's end date, must separate performance tests conducted every 3 years.

(2) For units demonstrating compliance through quarterly emission testing, you must conduct a performance test in the 4th quarter of a calendar year if your EGU has skipped performance tests in the first 3 quarters of the calendar year.

(3) If your EGU misses a performance test deadline due to being inoperative and if 168 or more boiler operating hours occur in the next test period, you must complete an additional performance test in that period as follows:

(i) At least 15 calendar days must separate two performance tests conducted in the same quarter.

(ii) At least 107 calendar days must separate two performance tests conducted in the same calendar year.

(iii) At least 350 calendar days must separate two performance tests conducted in the same 3 year period.

* * * * *

■ 10. Section 63.10007 is amended by revising paragraph (f)(2) to read as follows:

§ 63.10007 What methods and other procedures must I use for the performance tests?

* * * * *

(f) * * *

(2) *Default gross output.* If you use CEMS to continuously monitor Hg, HCl, HF, SO_2, or PM emissions (or, if applicable, sorbent trap monitoring systems to continuously collect Hg emissions data), the following default value is available for use in the emission rate calculations during startup periods or shutdown periods (as defined in § 63.10042). For the purposes of this subpart, this default value is not considered to be substitute data. For a startup or shutdown hour in which there is heat input to an affected EGU but zero gross output, you must calculate the pollutant emission rate using a value equivalent to 5% of the maximum sustainable gross output, expressed in megawatts, as defined in section 6.5.2.1(a)(1) of appendix A to part 75 of this chapter. This default gross output is either the nameplate capacity of the EGU or the highest gross output observed in at least four representative quarters of EGU operation. For a monitored common stack, the default gross output is used only when all EGUs are operating (*i.e.*, combusting fuel) are in startup or shutdown mode, and have zero electrical generation. Under those conditions, a default gross output equal to 5% of the combined maximum sustainable gross output of the EGUs that are operating but have a total of zero gross output must be used to calculate the hourly gross output-based pollutant emissions rate.

* * * * *

■ 11. Section 63.10009 is amended by revising paragraphs (a)(2) introductory text, (a)(2)(i), (b)(1) through (3), (e), (f) introductory text, (f)(2), (g), (j)(1)(ii), and (j)(2) introductory text to read as follows:

§ 63.10009 May I use emissions averaging to comply with this subpart?

(a) * * *

(2) You may demonstrate compliance by emissions averaging among the existing EGUs in the same subcategory, if your averaged Hg emissions for EGUs in the "unit designed for coal ≥8,300 Btu/lb" subcategory are equal to or less than 1.2 lb/TBtu or 1.3E–2 lb/GWh on a 30-boiler operating day basis or if your averaged emissions of individual, other pollutants from other subcategories of such EGUs are equal to or less than the applicable emissions limit in Table 2 to this subpart, according to the procedures in this section. Note that except for the alternate Hg emissions limit from EGUs in the "unit designed for coal ≥ 8,300 Btu/lb" subcategory, the averaging time for emissions averaging for pollutants is 30 days (rolling daily) using data from CEMS or a combination of data from CEMS and manual performance (LEE) testing. The averaging time for emissions averaging for the alternate Hg limit (equal to or less than 1.0 lb/TBtu or 1.1E–2 lb/GWh) from EGUs in the "unit designed for coal ≥ 8,300 Btu/lb" subcategory is 90-boiler operating days (rolling daily) using data from CEMS, sorbent trap monitoring, or a combination of monitoring data and data from manual performance (LEE) testing. For the purposes of this paragraph, 30- (or 90-) group boiler operating days is defined as a period during which at least one unit in the emissions averaging group operates on each of the 30 or 90 days. You must calculate the weighted average emissions rate for the group in accordance with the procedures in this paragraph using the data from all units in the group including any that operate fewer than 30 (or 90) days during the preceding 30 (or 90) group boiler days.

(i) You may choose to have your EGU emissions averaging group meet either the heat input basis (MMBtu or TBtu, as appropriate for the pollutant) or gross output basis (MWh or GWh, as appropriate for the pollutant).

* * * * *

(b) * * *

(1) *Group eligibility equations.*

$$WAER_m = \frac{\left[\sum_{j=1}^{p} Herm_j \times Rmm_j\right] + \sum_{k=1}^{m} Ter_k \times Rmt_k}{\left(\sum_{j=1}^{p} Rmm_j\right) + \sum_{k=1}^{m} Rmt_k} \qquad (Eq. 1a)$$

Where:

$WAER_m$ = Maximum Weighted Average Emission Rate in terms of lb/heat input or lb/gross output,

$Herm_{i,j}$ = hourly emission rate (*e.g.*, lb/MMBtu, lb/MWh) from CEMS or sorbent trap monitoring as determined during the initial compliance determination from EGU j,

Rmm_j = Maximum rated heat input, MMBtu/h, or maximum rated gross output, MWh/h, for EGU j,

p = number of EGUs in emissions averaging group that rely on CEMS,

Ter_k = Emissions rate (lb/MMBTU or lb/MWh) as determined during the initial compliance determination of EGU k,

Rmt_k = Maximum rated heat input, MMBtu/h, or maximum rated gross output, MWh/h, for EGU k, and

m = number of EGUs in emissions averaging group that rely on emissions testing.

$$WAER_m = \frac{\sum \left[\left(\sum_{j=1}^{p} Herm_{i,j}\right) \times Smm_j \times Cfm_{j_j}\right] + \sum_{k=1}^{m} Ter_k \times Smt_k \times Cft_k}{\sum \left[\sum_{j=1}^{p} Smm_j \times Cfm_j\right] + \sum_{k=1}^{m} Smt_k \times Cft_k} \quad (Eq.\ 1b)$$

Where:

Variables with the similar names share the descriptions for Equation 1a of this section,

Smm_j = maximum steam generation, lb_{steam}/h or lb/gross output, for EGU j,

Cfm_j = conversion factor, calculated from the most recent compliance test results, in terms units of heat output or gross output per pound of steam generated (MMBtu/lb_{steam} or MWh/lb_{steam}) from EGU j,

Smt_k = maximum steam generation, lb_{steam}/h or lb/gross output, for EGU k, and

Cfm_k = conversion factor, calculated from the most recent compliance test results, in terms units of heat output or gross output per pound of steam generated (MMBtu/lb_{steam} or MWh/lb_{steam}) from EGU k.

(2) Weighted 30-boiler operating day rolling average emissions rate equations for pollutants other than Hg. Use Equation 2a or 2b of this section to calculate the 30 day rolling average emissions daily.

$$WAER = \frac{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Her_i \times Rm_i)\right]_p + \sum_{i=1}^{m}(Ter_i \times Rt_i)}{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Rm_i)\right]_p + \sum_{i=1}^{m} Rt_i} \quad (Eq.\ 2a)$$

Where:

Her_i = hourly emission rate (*e.g.*, lb/MMBtu, lb/MWh) from unit i's CEMS for the preceding 30-group boiler operating days,

Rm_i = hourly heat input or gross output from unit i for the preceding 30-group boiler operating days,

p = number of EGUs in emissions averaging group that rely on CEMS or sorbent trap monitoring,

n = number of hours that hourly rates are collected over 30-group boiler operating days,

Ter_i = Emissions rate from most recent emissions test of unit i in terms of lb/heat input or lb/gross output,

Rt_i = Total heat input or gross output of unit i for the preceding 30-boiler operating days, and

m = number of EGUs in emissions averaging group that rely on emissions testing.

$$WAER = \frac{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Her_i \times Sm_i \times Cfm_i)\right]_p + \sum_{i=1}^{m}(Ter_i \times St_i \times Cft_i)}{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Sm_i \times Cfm_i)\right]_p + \sum_{i=1}^{m} St_i \times Cft_i} \quad (Eq.2b)$$

Where:

variables with similar names share the descriptions for Equation 2a of this section,

Sm_i = steam generation in units of pounds from unit i that uses CEMS for the preceding 30-group boiler operating days,

Cfm_i = conversion factor, calculated from the most recent compliance test results, in units of heat input per pound of steam generated or gross output per pound of steam generated, from unit i that uses CEMS from the preceding 30 group boiler operating days,

St_i = steam generation in units of pounds from unit i that uses emissions testing, and

Cft_i = conversion factor, calculated from the most recent compliance test results, in units of heat input per pound of steam generated or gross output per pound of steam generated, from unit i that uses emissions testing.

(3) Weighted 90-boiler operating day rolling average emissions rate equations for Hg emissions from EGUs in the "coal-fired unit not low rank virgin coal" subcategory. Use Equation 3a or 3b of this section to calculate the 90-day rolling average emissions daily.

$$WAER = \frac{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Her_i \times Rm_i)\right]_p + \sum_{i=1}^{m}(Ter_i \times Rt_i)}{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Rm_i)\right]_p + \sum_{i=1}^{m} Rt_i} \quad (Eq.3a)$$

Where:

Her_i = hourly emission rate from unit i's CEMS or Hg sorbent trap monitoring system for the preceding 90-group boiler operating days,

Rm_i = hourly heat input or gross output from unit i for the preceding 90-group boiler operating days,

p = number of EGUs in emissions averaging group that rely on CEMS,

n = number of hours that hourly rates are collected over the 90-group boiler operating days,

Ter_i = Emissions rate from most recent emissions test of unit i in terms of lb/heat input or lb/gross output,

Rt_i = Total heat input or gross output of unit i for the preceding 90-boiler operating days, and

m = number of EGUs in emissions averaging group that rely on emissions testing.

$$WAER = \frac{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Her_i \times Sm_i \times Cfm_i)\right]_p + \sum_{i=1}^{m}(Ter_i \times St_i \times Cft_i)}{\sum_{i=1}^{p}\left[\sum_{i=1}^{n}(Sm_i \times Cfm_i)\right]_p + \sum_{i=1}^{m} St_i \times Cft_i} \quad (Eq.3b)$$

Where:

variables with similar names share the descriptions for Equation 2a of this section,

Sm_i = steam generation in units of pounds from unit i that uses CEMS or a Hg sorbent trap monitoring for the preceding 90-group boiler operating days,

Cfm_i = conversion factor, calculated from the most recent compliance test results, in units of heat input per pound of steam generated or gross output per pound of steam generated, from unit i that uses CEMS or sorbent trap monitoring from the preceding 90-group boiler operating days,

St_i = steam generation in units of pounds from unit i that uses emissions testing, and

Cft_i = conversion factor, calculated from the most recent emissions test results, in units of heat input per pound of steam generated or gross output per pound of steam generated, from unit i that uses emissions testing.

* * * * *

(e) The weighted-average emissions rate from the existing EGUs participating in the emissions averaging option must be in compliance with the limits in Table 2 to this subpart at all times following the date that you begin emissions averaging.

(f) Emissions averaging group eligibility demonstration. You must demonstrate the ability for the EGUs included in the emissions averaging group to demonstrate initial compliance according to paragraph (f)(1) or (2) of this section using the maximum rated heat input or gross output over a 30- (or 90-) boiler operating day period of each EGU and the results of the initial performance tests. For this demonstration and prior to preparing your emissions averaging plan, you must conduct required emissions monitoring for 30- (or 90-) days of boiler operation and any required manual performance testing to calculate maximum weighted average emissions rate in accordance with this section. If, before the start of your initial compliance demonstration, the Administrator becomes aware that you intend to use emissions averaging for that demonstration, or if your initial Notification of Compliance Status (NOCS) indicates that you intend to implement emissions averaging at a future date, the Administrator may require you to submit your proposed emissions averaging plan and supporting data for approval. If the Administrator requires approval of your plan, you may not begin using emissions averaging until the Administrator approves your plan.

* * * * *

(2) If you are not capable of monitoring heat input or gross output, and the EGU generates steam for purposes other than generating electricity, you may use Equation 1b of paragraph (b) of this section as an alternative to using Equation 1a of paragraph (b) of this section to demonstrate that the maximum weighted average emissions rates of filterable PM, HF, SO_2, HCl, non-Hg HAP metals, or Hg emissions from the existing units participating in the emissions averaging group do not exceed the emission limits in Table 2 to this subpart.

(g) You must determine the weighted average emissions rate in units of the applicable emissions limit on a 30 group boiler operating day rolling average basis (or, if applicable, on a 90 group boiler operating day rolling average basis for Hg) according to paragraphs (g)(1) and (2) of this section. The first averaging period ends on the 30th (or, if applicable, 90th for the alternate Hg emission limit) group boiler operating day after the date that you begin emissions averaging.

(1) You must use Equation 2a or 3a of paragraph (b) of this section to calculate the weighted average emissions rate using the actual heat input or gross output for each existing unit participating in the emissions averaging option.

(2) If you are not capable of monitoring heat input or gross output, you may use Equation 2b or 3b of paragraph (b) of this section as an alternative to using Equation 2a of paragraph (b) of this section to calculate the average weighted emission rate using the actual steam generation from the units participating in the emissions averaging option.

* * * * *

(j) * * *

(1) * * *

(ii) The process weighting parameter (heat input, gross output, or steam generated) that will be monitored for each averaging group;

* * * * *

(2) If, as described in paragraph (f) of this section, the Administrator requests you to submit the averaging plan for review and approval, you must receive approval before initiating emissions averaging.

* * * * *

■ 12. Section 63.10010 is amended by revising paragraphs (a)(4), (f)(3) and (4), (h)(6)(i) and (ii), (i)(5)(i)(A) and (B), (j)(1)(i), (j)(4)(i)(A) and (B), and (l) to read as follows:

§ 63.10010 What are my monitoring, installation, operation, and maintenance requirements?

(a) * * *

(4) *Unit with a main stack and a bypass stack that exhausts to the atmosphere independent of the main stack.* If the exhaust configuration of an affected unit consists of a main stack and a bypass stack, you shall install CEMS on both the main stack and the bypass stack. If it is not feasible to certify and quality-assure the data from a monitoring system on the bypass stack, you shall:

(i) Route the exhaust from the bypass through the main stack and its monitoring so that bypass emissions are measured; or

(ii) Install a CEMS only on the main stack and count hours that the bypass stack is in use as hours of deviation from the monitoring requirements.

* * * * *

(f) * * *

(3) Calculate and record a 30-boiler operating day rolling average SO_2 emission rate in the units of the standard, updated after each new boiler operating day. Each 30-boiler operating day rolling average emission rate is the average of all of the valid hourly SO_2 emission rates in the 30 boiler operating day period.

(4) Use only unadjusted, quality-assured SO_2 concentration values in the emissions calculations; do not apply bias adjustment factors to the part 75 SO_2 data and do not use part 75 substitute data values. For startup or shutdown hours (as defined in § 63.10042) the default gross output and the diluent cap are available for use in the hourly SO_2 emission rate calculations, as described in § 63.10007(f). Use a flag to identify each startup or shutdown hour and report a special code if the diluent cap or default gross output is used to calculate the SO_2 emission rate for any of these hours.

* * * * *

(h) * * *

(6) * * *

(i) Any data collected during periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities that temporarily interrupt the measurement of output data from the PM CPMS. You must report any monitoring system malfunctions or out of control periods in your annual deviation reports. You must report any monitoring system quality assurance or quality control activities per the requirements of § 63.10031(b);

(ii) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods. You must report any such periods in your annual deviation report;

* * * * *

(i) * * *

(5) * * *

(i) * * *

(A) Any data collected during periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities that temporarily interrupt the measurement of emissions (*e.g.*, calibrations, certain audits). You must report any monitoring system malfunctions or out of control periods in your annual deviation reports. You must report any monitoring system quality assurance or quality control activities per the requirements of § 63.10031(b);

(B) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods. You must report any such periods in your annual deviation report;

* * * * *

(j) * * *

(1)(i) Install, calibrate, operate, and maintain your HAP metals CEMS according to your CMS quality control program, as described in § 63.8(d)(2). The reportable measurement output from the HAP metals CEMS must be expressed in units of the applicable emissions limit (*e.g.*, lb/MMBtu, lb/MWh) and in the form of a 30-boiler operating day rolling average.

* * * * *

(4) * * *

(i) * * *

(A) Any data collected during periods of monitoring system malfunctions, repairs associated with monitoring system malfunctions, or required monitoring system quality assurance or quality control activities that temporarily interrupt the measurement of emissions (*e.g.,* calibrations, certain audits). You must report any monitoring system malfunctions or out of control periods in your annual deviation reports. You must report any monitoring system quality assurance or quality control activities per the requirements of § 63.10031(b);

(B) Any data collected during periods when the monitoring system is out of control as specified in your site-specific monitoring plan, repairs associated with periods when the monitoring system is out of control, or required monitoring system quality assurance or quality control activities conducted during out-of-control periods. You must report any monitoring system malfunctions or out of control periods in your annual deviation reports. You must report any monitoring system quality assurance or quality control activities per the requirements of § 63.10031(b);

* * * * *

(l) Should you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU, you must install, verify, operate, maintain, and quality assure each monitoring system necessary for demonstrating compliance with the PM or non-mercury metals work practice standards required to comply with § 63.10020(e).

(1) You shall develop a site-specific monitoring plan for PM or non-mercury metals work practice monitoring during startup periods.

(2) You shall submit the site-specific monitoring plan upon request by the Administrator.

(3) The provisions of the monitoring plan must address the following items:

(i) Monitoring system installation;

(ii) Performance and equipment specifications;

(iii) Schedule for initial and periodic performance evaluations;

(iv) Performance evaluation procedures and acceptance criteria;

(v) On-going operation and maintenance procedures; and

(vi) On-going recordkeeping and reporting procedures.

(4) You may rely on monitoring system specifications or instructions or manufacturer's specifications to address paragraphs (l)(3)(i) through (vi) of this section.

(5) You must operate and maintain the monitoring system according to the site-specific monitoring plan.

■ 13. Section 63.10011 is amended by revising paragraphs (b), (c), (e), and (g) to read as follows:

§ 63.10011 How do I demonstrate initial compliance with the emissions limits and work practice standards?

* * * * *

(b) If you are subject to an operating limit in Table 4 to this subpart, you demonstrate initial compliance with HAP metals or filterable PM emission limit(s) through performance stack tests and you elect to use a PM CPMS to demonstrate continuous performance, or if, for a liquid oil-fired EGU, and you use quarterly stack testing for HCl and HF plus site-specific parameter monitoring to demonstrate continuous performance, you must also establish a site-specific operating limit, in accordance with § 63.10007 and Table 6 to this subpart. You may use only the parametric data recorded during successful performance tests (*i.e.,* tests that demonstrate compliance with the applicable emissions limits) to establish an operating limit.

(c)(1) If you use CEMS or sorbent trap monitoring systems to measure a HAP (*e.g.,* Hg or HCl) directly, the initial performance test, shall consist of a 30-boiler operating day (or, for certain coal-fired, existing EGUs that use emissions averaging for Hg, a 90-boiler operating day) rolling average emissions rate obtained with a certified CEMS or sorbent trap system, expressed in units of the standard. If the monitoring system is certified prior to the applicable compliance date, the initial averaging period shall either begin with: The first boiler operating day on or after the compliance date; or 30 (or, if applicable, 90) boiler operating days prior to that date, as described in § 63.10005(b). In all cases, the initial 30- or 90-boiler operating day averaging period must be completed on or before the date that compliance must be demonstrated, in accordance with § 63.9984(f). Initial compliance is demonstrated if the results of the performance test meet the applicable emission limit in Table 1 or 2 to this subpart.

(2) For an EGU that uses a CEMS to measure SO_2 or PM emissions for initial compliance, the initial performance test shall consist of a 30-boiler operating day average emission rate obtained with certified CEMS, expressed in units of the standard. If the monitoring system is certified prior to the applicable compliance date, the initial averaging period shall either begin with: The first boiler operating day on or after the compliance date; or 30 boiler operating days prior to that date, as described in § 63.10005(b). In all cases, the initial 30-boiler operating day averaging period must be completed on or before the date that compliance must be demonstrated, in accordance with § 63.9984(f). Initial compliance is demonstrated if the results of the performance test meet the applicable SO_2 or PM emission limit in Table 1 or 2 to this subpart.

* * * * *

(e) You must submit a Notification of Compliance Status containing the results of the initial compliance demonstration, in accordance with § 63.10030(e).

* * * * *

(g) You must follow the startup or shutdown requirements as established in Table 3 to this subpart for each coal-fired, liquid oil-fired, or solid oil-derived fuel-fired EGU.

(1) You may use the diluent cap and default gross output values, as described in § 63.10007(f), during startup periods or shutdown periods.

(2) You must operate all CMS, collect data, calculate pollutant emission rates, and record data during startup periods or shutdown periods.

(3) You must report the information as required in § 63.10031.

(4) If you choose to use paragraph (2) of the definition of "startup" in § 63.10042 and you find that you are unable to safely engage and operate your particulate matter (PM) control(s) within 1 hour of first firing of coal, residual oil, or solid oil-derived fuel, you may choose to rely on paragraph (1) of definition of "startup" in § 63.10042 or you may submit a request to use an alternative non-opacity emissions standard, as described below.

(i) As mentioned in § 63.6(g)(1), your request will be published in the **Federal Register** for notice and comment rulemaking. Until promulgation in the **Federal Register** of the final alternative non-opacity emission standard, you shall comply with paragraph (1) of the definition of "startup" in § 63.10042. You shall not implement the alternative non-opacity emissions standard until promulgation in the **Federal Register** of the final alternative non-opacity emission standard.

(ii) Your request need not address the items contained in § 63.6(g)(2).

(iii) Your request shall provide evidence of a documented manufacturer-identified safety issue.

(iv) Your request shall provide information to document that the PM control device is adequately designed and sized to meet the PM emission limit applicable to the EGU.

(v) In addition, your request shall contain documentation that:

(A) Your EGU is using clean fuels to the maximum extent possible, taking into account considerations such as not compromising boiler or control device integrity, to bring your EGU and PM control device up to the temperature necessary to alleviate or prevent the identified safety issues prior to the combustion of primary fuel in your EGU;

(B) You have followed explicitly your EGU manufacturer's procedures to alleviate or prevent the identified safety issue; and

(C) You have identified with specificity the details of your EGU manufacturer's statement of concern.

(vi) Your request shall specify the other work practice standards you will take to limit HAP emissions during startup periods and shutdown periods to ensure a control level consistent with the work practice standards of the final rule.

(vii) You must comply with all other work practice requirements, including but not limited to data collection, recordkeeping, and reporting requirements.

■ 14. Section 63.10020 is amended by revising paragraph (e) to read as follows:

§ 63.10020 How do I monitor and collect data to demonstrate continuous compliance?

* * * * *

(e) Additional requirements during startup periods or shutdown periods if you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU.

(1) During each period of startup, you must record for each EGU:

(i) The date and time that clean fuels being combusted for the purpose of startup begins;

(ii) The quantity and heat input of clean fuel for each hour of startup;

(iii) The gross output for each hour of startup;

(iv) The date and time that non-clean fuel combustion begins; and

(v) The date and time that clean fuels being combusted for the purpose of startup ends.

(2) During each period of shutdown, you must record for each EGU:

(i) The date and time that clean fuels being combusted for the purpose of shutdown begins;

(ii) The quantity and heat input of clean fuel for each hour of shutdown;

(iii) The gross output for each hour of shutdown;

(iv) The date and time that non-clean fuel combustion ends; and

(v) The date and time that clean fuels being combusted for the purpose of shutdown ends.

(3) For PM or non-mercury HAP metals work practice monitoring during startup periods, you must monitor and collect data according to this section and the site-specific monitoring plan required by § 63.10010(l).

(i) Except for an EGU that uses PM CEMS or PM CPMS to demonstrate compliance with the PM emissions limit, or that has LEE status for filterable PM or total non-Hg HAP metals for non-liquid oil-fired EGUs (or HAP metals emissions for liquid oil-fired EGUs), or individual non-mercury metals CEMS, you must:

(A) Record temperature and combustion air flow or calculated flow as determined from combustion equations of post-combustion (exhaust) gas, as well as amperage of forced draft fan(s), upstream of the filterable PM control devices during each hour of startup.

(B) Record temperature and flow of exhaust gas, as well as amperage of any induced draft fan(s), downstream of the filterable PM control devices during each hour of startup.

(C) For an EGU with an electrostatic precipitator, record the number of fields in service, as well as each field's secondary voltage and secondary current during each hour of startup.

(D) For an EGU with a fabric filter, record the number of compartments in service, as well as the differential pressure across the baghouse during each hour of startup.

(E) For an EGU with a wet scrubber needed for filterable PM control, record the scrubber liquid to flue gas ratio and the pressure drop across the scrubber during each hour of startup.

(ii) [Reserved]

■ 15. Section 63.10021 is amended by revising paragraphs (d)(3), (e) introductory text, (e)(9), and (h)(1) to read as follows:

§ 63.10021 How do I demonstrate continuous compliance with the emission limitations, operating limits, and work practice standards?

* * * * *

(d) * * *

(3) Must conduct site-specific monitoring using CMS to demonstrate compliance with the site-specific monitoring requirements in Table 7 to this subpart pertaining to HCl and HF emissions from a liquid oil-fired EGU to ensure compliance with the HCl and HF emission limits in Tables 1 and 2 to this subpart, in accordance with the requirements of § 63.10000(c)(2)(iii). The monitoring must meet the general operating requirements provided in § 63.10020.

(e) Conduct periodic performance tune-ups of your EGU(s), as specified in paragraphs (e)(1) through (9) of this section. For your first tune-up, you may perform the burner inspection any time prior to the tune-up or you may delay the first burner inspection until the next scheduled EGU outage provided you meet the requirements of § 63.10005. Subsequently, you must perform an inspection of the burner at least once every 36 calendar months unless your EGU employs neural network combustion optimization during normal operations in which case you must perform an inspection of the burner and combustion controls at least once every 48 calendar months. If your EGU is offline when a deadline to perform the tune-up passes, you shall perform the tune-up work practice requirements within 30 days after the re-start of the affected unit.

* * * * *

(9) Report the dates of the initial and subsequent tune-ups in hard copy, as specified in § 63.10031(f)(5), until April 16, 2017. After April 16, 2017, report the date of all tune-ups electronically, in accordance with § 63.10031(f). The tune-up report date is the date when tune-up requirements in paragraphs (e)(6) and (7) of this section are completed.

* * * * *

(h) * * *

(1) You may use the diluent cap and default gross output values, as described in § 63.10007(f), during startup periods or shutdown periods.

* * * * *

■ 16. Section 63.10023 is amended by removing and reserving paragraph (b)(1) and revising paragraph (b)(2) introductory text to read as follows:

§ 63.10023 How do I establish my PM CPMS operating limit and determine compliance with it?

* * * * *

(b) * * *

(2) Determine your operating limit as follows:

* * * * *

■ 17. Section 63.10030 is amended by:

■ a. Revising paragraphs (e)(1) and (e)(7)(i);

■ b. Adding paragraph (e)(7)(iii);

■ c. Revising paragraph (e)(8); and

■ d. Adding paragraph (f).

The revisions and additions read as follows:

§ 63.10030 What notifications must I submit and when?

* * * * *

(e) * * *

(1) A description of the affected source(s), including identification of the subcategory of the source, the design capacity of the source, a description of the add-on controls used on the source, description of the fuel(s) burned, including whether the fuel(s) were determined by you or EPA through a

petition process to be a non-waste under 40 CFR 241.3, whether the fuel(s) were processed from discarded non-hazardous secondary materials within the meaning of 40 CFR 241.3, and justification for the selection of fuel(s) burned during the performance test.

* * * * *

(7) * * *

(i) A summary of the results of the annual performance tests and documentation of any operating limits that were reestablished during this test, if applicable. If you are conducting stack tests once every 3 years consistent with § 63.10005(h)(1)(i), the date of each stack test conducted during the previous 3 years, a comparison of emission level you achieved in each stack test conducted during the previous 3 years to the 50 percent emission limit threshold required in § 63.10006(i), and a statement as to whether there have been any operational changes since the last stack test that could increase emissions.

* * * * *

(iii) For each of your existing EGUs, identification of each emissions limit as specified in Table 2 to this subpart with which you plan to comply.

(A) You may switch from a mass per heat input to a mass per gross output limit (or vice-versa), provided that:

(*1*) You submit a request that identifies for each EGU or EGU emissions averaging group involved in the proposed switch both the current and proposed emission limit;

(*2*) Your request arrives to the Administrator at least 30 calendar days prior to the date that the switch is proposed to occur;

(*3*) Your request demonstrates through performance stack test results completed within 30 days prior to your submission, compliance for each EGU or EGU emissions averaging group with both the mass per heat input and mass per gross output limits;

(*4*) You revise and submit all other applicable plans, *e.g.*, monitoring and emissions averaging, with your request; and

(*5*) You maintain records of all information regarding your choice of emission limits.

(B) You begin to use the revised emission limits starting in the next reporting period, after receipt of written acknowledgement from the Administrator of the switch.

(C) From submission of your request until start of the next reporting period after receipt of written acknowledgement from the Administrator of the switch, you demonstrate compliance with both the mass per heat input and mass per gross output emission limits for each pollutant for each EGU or EGU emissions averaging group.

(8) Identification of whether you plan to rely on paragraph (1) or (2) of the definition of "startup" in § 63.10042.

(i) Should you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU, you shall include a report that identifies:

(A) The original EGU installation date;

(B) The original EGU design characteristics, including, but not limited to, fuel mix and PM controls;

(C) Each design PM control device efficiency established during performance testing or while operating in periods other than startup and shutdown periods;

(D) The design PM emission rate from the EGU in terms of pounds PM per MMBtu and pounds PM per hour established during performance testing or while operating in periods other than startup and shutdown periods;

(E) The design time from start of fuel combustion to necessary conditions for each PM control device startup;

(F) Each design PM control device efficiency upon startup of the PM control device, if different from the efficiency provided in paragraph (e)(8)(i)(C) of this section;

(G) Current EGU PM producing characteristics, including, but not limited to, fuel mix and PM controls, if different from the characteristics provided in paragraph (e)(8)(i)(B) of this section;

(H) Current PM control device efficiency from each PM control device, if different from the efficiency provided in paragraph (e)(8)(i)(C) of this section;

(I) Current PM emission rate from the EGU in terms of pounds PM per MMBtu and pounds per hour, if different from the rate provided in paragraph (e)(8)(i)(D) of this section;

(J) Current time from start of fuel combustion to conditions necessary for each PM control device startup, if different from the time provided in paragraph (e)(8)(i)(E) of this section; and

(K) Current PM control device efficiency upon startup of each PM control device, if different from the efficiency provided in paragraph (e)(8)(i)(H) of this section.

(ii) The report shall be prepared, signed, and sealed by a professional engineer licensed in the state where your EGU is located.

(iii) You may switch from paragraph (1) of the definition of "startup" in § 63.10042 to paragraph (2) of the definition of "startup" (or vice-versa), provided that:

(A) You submit a request that identifies for each EGU or EGU emissions averaging group involved in the proposed switch both the current definition of "startup" relied on and the proposed definition you plan to rely on;

(B) Your request arrives to the Administrator at least 30 calendar days prior to the date that the switch is proposed to occur;

(C) You revise and submit all other applicable plans, *e.g.*, monitoring and emissions averaging, with your submission;

(D) You maintain records of all information regarding your choice of the definition of "startup"; and

(E) You begin to use the revised definition of "startup" in the next reporting period after receipt of written acknowledgement from the Administrator of the switch.

(f) You must submit the notifications in § 63.10000(h)(2) and (i)(2) that may apply to you by the dates specified.

■ 18. Section 63.10031 is amended by revising paragraphs (c) introductory text and (c)(4) and (5) and adding paragraphs (c)(6), (7), (8), and (9) to read as follows:

§ 63.10031 What reports must I submit and when?

* * * * *

(c) The compliance report must contain the information required in paragraphs (c)(1) through (9) of this section.

* * * * *

(4) Include the date of the most recent tune-up for each EGU. The date of the tune-up is the date the tune-up provisions specified in § 63.10021(e)(6) and (7) were completed.

(5) Should you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU, for each instance of startup or shutdown you shall:

(i) Include the maximum clean fuel storage capacity and the maximum hourly heat input that can be provided for each clean fuel determined according to the requirements of § 63.10032(f).

(ii) Include the information required to be monitored, collected, or recorded according to the requirements of § 63.10020(e).

(iii) If you choose to use CEMS to demonstrate compliance with numerical limits, include hourly average CEMS values and hourly average flow values during startup periods or shutdown periods. Use units of milligrams per cubic meter for PM CEMS values, micrograms per cubic meter for Hg CEMS values, and ppmv for HCl, HF, or

SO_2 CEMS values. Use units of standard cubic meters per hour on a wet basis for flow values.

(iv) If you choose to use a separate sorbent trap measurement system for startup or shutdown reporting periods, include hourly average mercury concentration values in terms of micrograms per cubic meter.

(v) If you choose to use a PM CPMS, include hourly average operating parameter values in terms of the operating limit, as well as the operating parameter to PM correlation equation.

(6) You must report emergency bypass information annually from EGUs with LEE status.

(7) A summary of the results of the annual performance tests and documentation of any operating limits that were reestablished during the test, if applicable. If you are conducting stack tests once every 3 years to maintain LEE status, consistent with § 63.10006(b), the date of each stack test conducted during the previous 3 years, a comparison of emission level you achieved in each stack test conducted during the previous 3 years to the 50 percent emission limit threshold required in § 63.10005(h)(1)(i), and a statement as to whether there have been any operational changes since the last stack test that could increase emissions.

(8) A certification.

(9) If you have a deviation from any emission limit, work practice standard, or operating limit, you must also submit a brief description of the deviation, the duration of the deviation, emissions point identification, and the cause of the deviation.

* * * * *

■ 19. Section 63.10032 is amended by revising paragraph (f) to read as follows:

§ 63.10032 What records must I keep?

* * * * *

(f) Regarding startup periods or shutdown periods:

(1) Should you choose to rely on paragraph (1) of the definition of "startup" in § 63.10042 for your EGU, you must keep records of the occurrence and duration of each startup or shutdown.

(2) Should you choose to rely on paragraph (2) of the definition of "startup" in § 63.10042 for your EGU, you must keep records of:

(i) The determination of the maximum possible clean fuel capacity for each EGU;

(ii) The determination of the maximum possible hourly clean fuel heat input and of the hourly clean fuel heat input for each EGU; and

(iii) The information required in § 63.10020(e).

* * * * *

■ 20. Section 63.10042 is amended by:

■ a. Revising the definitions of "Coal-fired electric utility steam generating unit," "Coal refuse," "Fossil fuel-fired," "Integrated gasification combined cycle electric utility steam generating unit or IGCC," "Limited-use liquid oil-fired subcategory," and "Natural gas-fired electric utility steam generating unit";

■ b. Adding, in alphabetical order, definition of "Neural network or neural net"; and

■ c. Revising the definition of "Oil-fired electric utility steam generating unit."

The revisions and additions read as follows:

§ 63.10042 What definitions apply to this subpart?

* * * * *

Coal-fired electric utility steam generating unit means an electric utility steam generating unit meeting the definition of "fossil fuel-fired" that burns coal for more than 10.0 percent of the average annual heat input during the 3 previous calendar years after the compliance date for your facility in § 63.9984 or for more than 15.0 percent of the annual heat input during any one of those calendar years. EGU owners and operators must estimate coal, oil, and natural gas usage for the first 3 calendar years after the applicable compliance date and they are solely responsible for assuring compliance with this final rule or other applicable standard based on their fuel usage projections. After the first 3 years of compliance, EGUs are required to evaluate applicability based on coal or oil usage from the three previous calendars years on an annual rolling basis.

Coal refuse means waste products of coal mining, physical coal cleaning, and coal preparation operations (*e.g.* culm, gob, etc.) containing coal, matrix material, clay, and other organic and inorganic material.

* * * * *

Fossil fuel-fired means an electric utility steam generating unit (EGU) that is capable of producing more than 25 MW of electrical output from the combustion of fossil fuels. To be "capable of combusting" fossil fuels, an EGU would need to have these fuels allowed in its operating permit and have the appropriate fuel handling facilities on-site or otherwise available (*e.g.,* coal handling equipment, including coal storage area, belts and conveyers, pulverizers, etc.; oil storage facilities). In addition, fossil fuel-fired means any EGU that fired fossil fuels for more than 10.0 percent of the average annual heat input during the 3 previous calendar years after the compliance date for your facility in § 63.9984 or for more than 15.0 percent of the annual heat input during any one of those calendar years. EGU owners and operators must estimate coal, oil, and natural gas usage for the first 3 calendar years after the applicable compliance date and they are solely responsible for assuring compliance with this final rule or other applicable standard based on their fuel usage projections. After the first 3 years of compliance, EGUs are required to evaluate applicability based on coal or oil usage from the three previous calendars years on an annual rolling basis.

* * * * *

Integrated gasification combined cycle electric utility steam generating unit or *IGCC* means an electric utility steam generating unit meeting the definition of "fossil fuel-fired" that burns a synthetic gas derived from coal and/or solid oil-derived fuel for more than 10.0 percent of the average annual heat input during the 3 previous calendar years after the compliance date for your facility in § 63.9984 or for more than 15.0 percent of the annual heat input during any one of those calendar years in a combined-cycle gas turbine. EGU owners and operators must estimate coal, oil, and natural gas usage for the first 3 calendar years after the applicable compliance date and they are solely responsible for assuring compliance with this final rule or other applicable standard based on their fuel usage projections. No solid coal or solid oil-derived fuel is directly burned in the unit during operation. After the first 3 years of compliance, EGUs are required to evaluate applicability based on coal or oil usage from the three previous calendars years on an annual rolling basis.

* * * * *

Limited-use liquid oil-fired subcategory means an oil-fired electric utility steam generating unit with an annual capacity factor when burning oil of less than 8 percent of its maximum or nameplate heat input, whichever is greater, averaged over a 24-month block contiguous period commencing on the first of the month following the compliance date specified in § 63.9984.

* * * * *

Natural gas-fired electric utility steam generating unit means an electric utility steam generating unit meeting the definition of "fossil fuel-fired" that is not a coal-fired, oil-fired, or IGCC electric utility steam generating unit and that burns natural gas for more than 10.0 percent of the average annual heat input during the 3 previous calendar years after the compliance date for your facility in § 63.9984 or for more than 15.0 percent of the annual heat input during any one of those calendar years. EGU owners and operators must estimate coal, oil, and natural gas usage for the first 3 calendar years after the applicable compliance date and they are solely responsible for assuring compliance with this final rule or other applicable standard based on their fuel usage projections.

* * * * *

Neural network or *neural net* for purposes of this rule means an automated boiler optimization system. A neural network typically has the ability to process data from many inputs to develop, remember, update, and enable algorithms for efficient boiler operation.

* * * * *

Oil-fired electric utility steam generating unit means an electric utility steam generating unit meeting the definition of "fossil fuel-fired" that is not a coal-fired electric utility steam generating unit and that burns oil for more than 10.0 percent of the average annual heat input during the 3 previous calendar years after the compliance date for your facility in § 63.9984 or for more than 15.0 percent of the annual heat input during any one of those calendar years. EGU owners and operators must estimate coal, oil, and natural gas usage for the first 3 calendar years after the applicable compliance date and they are solely responsible for assuring compliance with this final rule or other applicable standard based on their fuel usage projections. After the first 3 years of compliance, EGUs are required to evaluate applicability based on coal or oil usage from the three previous calendars years on an annual rolling basis.

* * * * *

■ 21. Revise Table 1 to subpart UUUUU of part 63 to read as follows:

TABLE 1 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR NEW OR RECONSTRUCTED EGUS

[As stated in § 63.9991, you must comply with the following applicable emission limits:]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.,* specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
1. Coal-fired unit not low rank virgin coal.	a. Filterable particulate matter (PM).	9.0E-2 lb/MWh[1]	Collect a minimum of 4 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	6.0E-2 lb/GWh	Collect a minimum of 4 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E-3 lb/GWh	
	Arsenic (As)	3.0E-3 lb/GWh	
	Beryllium (Be)	6.0E-4 lb/GWh	
	Cadmium (Cd)	4.0E-4 lb/GWh	
	Chromium (Cr)	7.0E-3 lb/GWh	
	Cobalt (Co)	2.0E-3 lb/GWh	
	Lead (Pb)	2.0E-2 lb/GWh	
	Manganese (Mn)	4.0E-3 lb/GWh	
	Nickel (Ni)	4.0E-2 lb/GWh	
	Selenium (Se)	5.0E-2 lb/GWh	
	b. Hydrogen chloride (HCl)	1.0E-2 lb/MWh	For Method 26A at appendix A–8 to part 60 of this chapter, collect a minimum of 3 dscm per run. For ASTM D6348–03[2] or Method 320 at appendix A to part 63 of this chapter, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2)[3]	1.0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	3.0E-3 lb/GWh	Hg CEMS or sorbent trap monitoring system only.
2. Coal-fired units low rank virgin coal.	a. Filterable particulate matter (PM).	9.0E-2 lb/MWh[1]	Collect a minimum of 4 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	6.0E-2 lb/GWh	Collect a minimum of 4 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E-3 lb/GWh	
	Arsenic (As)	3.0E-3 lb/GWh	
	Beryllium (Be)	6.0E-4 lb/GWh	
	Cadmium (Cd)	4.0E-4 lb/GWh	
	Chromium (Cr)	7.0E-3 lb/GWh	
	Cobalt (Co)	2.0E-3 lb/GWh	
	Lead (Pb)	2.0E-2 lb/GWh	
	Manganese (Mn)	4.0E-3 lb/GWh	
	Nickel (Ni)	4.0E-2 lb/GWh	
	Selenium (Se)	5.0E-2 lb/GWh	
	b. Hydrogen chloride (HCl)	1.0E-2 lb/MWh	For Method 26A, collect a minimum of 3 dscm per run For ASTM D6348–03[2] or Method 320, sample for a minimum of 1 hour.
	OR		

TABLE 1 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR NEW OR RECONSTRUCTED EGUs—Continued

[As stated in § 63.9991, you must comply with the following applicable emission limits:]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.,* specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
	Sulfur dioxide (SO_2)[3]	1.0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	4.0E-2 lb/GWh	Hg CEMS or sorbent trap monitoring system only.
3. IGCC unit	a. Filterable particulate matter (PM).	7.0E-2 lb/MWh[4] 9.0E–2 lb/MWh[5].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	4.0E-1 lb/GWh	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 2 dscm per run.
	Antimony (Sb)	2.0E-2 lb/GWh	
	Arsenic (As)	2.0E-2 lb/GWh	
	Beryllium (Be)	1.0E-3 lb/GWh	
	Cadmium (Cd)	2.0E-3 lb/GWh	
	Chromium (Cr)	4.0E-2 lb/GWh	
	Cobalt (Co)	4.0E-3 lb/GWh	
	Lead (Pb)	9.0E-3 lb/GWh	
	Manganese (Mn)	2.0E-2 lb/GWh	
	Nickel (Ni)	7.0E-2 lb/GWh	
	Selenium (Se)	3.0E-1 lb/GWh	
	b. Hydrogen chloride (HCl)	2.0E-3 lb/MWh	For Method 26A, collect a minimum of 1 dscm per run; for Method 26 at appendix A–8 to part 60 of this chapter, collect a minimum of 120 liters per run. For ASTM D6348–03[2] or Method 320, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2)[3]	4.0E-1 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	3.0E-3 lb/GWh	Hg CEMS or sorbent trap monitoring system only.
4. Liquid oil-fired unit—continental (excluding limited-use liquid oil-fired subcategory units).	a. Filterable particulate matter (PM).	3.0E-1 lb/MWh[1]	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total HAP metals	2.0E-4 lb/MWh	Collect a minimum of 2 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 2 dscm per run.
	Antimony (Sb)	1.0E-2 lb/GWh	
	Arsenic (As)	3.0E-3 lb/GWh	
	Beryllium (Be)	5.0E-4 lb/GWh	
	Cadmium (Cd)	2.0E-4 lb/GWh	
	Chromium (Cr)	2.0E-2 lb/GWh	
	Cobalt (Co)	3.0E-2 lb/GWh	
	Lead (Pb)	8.0E-3 lb/GWh	
	Manganese (Mn)	2.0E-2 lb/GWh	
	Nickel (Ni)	9.0E-2 lb/GWh	
	Selenium (Se)	2.0E-2 lb/GWh	
	Mercury (Hg)	1.0E-4 lb/GWh	For Method 30B at appendix A–8 to part 60 of this chapter sample volume determination (Section 8.2.4), the estimated Hg concentration should nominally be < ½ the standard.
	b. Hydrogen chloride (HCl)	4.0E-4 lb/MWh	For Method 26A, collect a minimum of 3 dscm per run. For ASTM D6348–03[2] or Method 320, sample for a minimum of 1 hour.
	c. Hydrogen fluoride (HF)	4.0E-4 lb/MWh	For Method 26A, collect a minimum of 3 dscm per run. For ASTM D6348–03[2] or Method 320, sample for a minimum of 1 hour.
5. Liquid oil-fired unit—noncontinental (excluding limited-use liquid oil-fired subcategory units).	a. Filterable particulate matter (PM).	2.0E–1 lb/MWh[1]	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total HAP metals	7.0E-3 lb/MWh	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.

TABLE 1 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR NEW OR RECONSTRUCTED EGUs—Continued

[As stated in § 63.9991, you must comply with the following applicable emission limits:]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.*, specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
	Antimony (Sb)	8.0E-3 lb/GWh	
	Arsenic (As)	6.0E-2 lb/GWh	
	Beryllium (Be)	2.0E-3 lb/GWh	
	Cadmium (Cd)	2.0E-3 lb/GWh	
	Chromium (Cr)	2.0E-2 lb/GWh	
	Cobalt (Co)	3.0E-1 lb/GWh	
	Lead (Pb)	3.0E-2 lb/GWh	
	Manganese (Mn)	1.0E-1 lb/GWh	
	Nickel (Ni)	4.1E0 lb/GWh	
	Selenium (Se)	2.0E-2 lb/GWh	
	Mercury (Hg)	4.0E-4 lb/GWh	For Method 30B sample volume determination (Section 8.2.4), the estimated Hg concentration should nominally be < ½ the standard.
	b. Hydrogen chloride (HCl)	2.0E-3 lb/MWh	For Method 26A, collect a minimum of 1 dscm per run;for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03 [2] or Method 320, sample for a minimum of 1 hour.
	c. Hydrogen fluoride (HF)	5.0E-4 lb/MWh	For Method 26A, collect a minimum of 3 dscm per run.For ASTM D6348–03 [2] or Method 320, sample for a minimum of 1 hour.
6. Solid oil-derived fuel-fired unit.	a. Filterable particulate matter (PM).	3.0E-2 lb/MWh [1]	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	6.0E-1 lb/GWh	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E–3 lb/GWh	
	Arsenic (As)	3.0E-3 lb/GWh	
	Beryllium (Be)	6.0E-4 lb/GWh	
	Cadmium (Cd)	7.0E-4 lb/GWh	
	Chromium (Cr)	6.0E-3 lb/GWh	
	Cobalt (Co)	2.0E-3 lb/GWh	
	Lead (Pb)	2.0E-2 lb/GWh	
	Manganese (Mn)	7.0E-3 lb/GWh	
	Nickel (Ni)	4.0E-2 lb/GWh	
	Selenium (Se)	6.0E-3 lb/GWh	
	b. Hydrogen chloride (HCl)	4.0E-4 lb/MWh	For Method 26A, collect a minimum of 3 dscm per run. For ASTM D6348–03 [2] or Method 320, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2) [3]	1.0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	2.0E-3 lb/GWh	Hg CEMS or Sorbent trap monitoring system only.

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[1] Gross output.

[2] Incorporated by reference, see § 63.14.

[3] You may not use the alternate SO_2 limit if your EGU does not have some form of FGD system (or, in the case of IGCC EGUs, some other acid gas removal system either upstream or downstream of the combined cycle block) and SO_2 CEMS installed.

[4] Duct burners on syngas; gross output.

[5] Duct burners on natural gas; gross output.

■ 22. Revise Table 2 to subpart UUUUU of part 63 to read as follows:

TABLE 2 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR EXISTING EGUs

[As stated in § 63.9991, you must comply with the following applicable emission limits: [1]]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.,* specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
1. Coal-fired unit not low rank virgin coal.	a. Filterable particulate matter (PM).	3.0E-2 lb/MMBtu or 3.0E-1 lb/MWh [2].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	5.0E-5 lb/MMBtu or 5.0E-1 lb/GWh.	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E-1 lb/TBtu or 8.0E-3 lb/GWh	
	Arsenic (As)	1.1E0 lb/TBtu or 2.0E-2 lb/GWh	
	Beryllium (Be)	2.0E-1 lb/TBtu or 2.0E-3 lb/GWh	
	Cadmium (Cd)	3.0E-1 lb/TBtu or 3.0E-3 lb/GWh	
	Chromium (Cr)	2.8E0 lb/TBtu or 3.0E-2 lb/GWh	
	Cobalt (Co)	8.0E-1 lb/TBtu or 8.0E-3 lb/GWh	
	Lead (Pb)	1.2E0 lb/TBtu or 2.0E-2 lb/GWh	
	Manganese (Mn)	4.0E0 lb/TBtu or 5.0E-2 lb/GWh	
	Nickel (Ni)	3.5E0 lb/TBtu or 4.0E-2 lb/GWh	
	Selenium (Se)	5.0E0 lb/TBtu or 6.0E-2 lb/GWh	
	b. Hydrogen chloride (HCl)	2.0E-3 lb/MMBtu or 2.0E-2 lb/MWh.	For Method 26A at appendix A–8 to part 60 of this chapter, collect a minimum of 0.75 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03 [3] or Method 320 at appendix A to part 63 of this chapter, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2) [4]	2.0E-1 lb/MMBtu or 1.5E0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	1.2E0 lb/TBtu or 1.3E-2 lb/GWh	LEE Testing for 30 days with a sampling period consistent with that given in section 5.2.1 of appendix A to this subpart per Method 30B at appendix A–8 to part 60 of this chapter run or Hg CEMS or sorbent trap monitoring system only.
		OR.	
		1.0E0 lb/TBtu or 1.1E-2 lb/GWh	LEE Testing for 90 days with a sampling period consistent with that given in section 5.2.1 of appendix A to this subpart per Method 30B run or Hg CEMS or sorbent trap monitoring system only.
2. Coal-fired unit low rank virgin coal.	a. Filterable particulate matter (PM).	3.0E-2 lb/MMBtu or 3.0E-1 lb/MWh [2].	Collect a minimum of 1 dscm per run.
	OR	OR.	
	Total non-Hg HAP metals	5.0E-5 lb/MMBtu or 5.0E-1 lb/GWh.	Collect a minimum of 1 dscm per run.
	OR	OR.	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E-1 lb/TBtu or 8.0E-3 lb/GWh	
	Arsenic (As)	1.1E0 lb/TBtu or 2.0E-2 lb/GWh	
	Beryllium (Be)	2.0E-1 lb/TBtu or 2.0E-3 lb/GWh	
	Cadmium (Cd)	3.0E-1 lb/TBtu or 3.0E-3 lb/GWh	
	Chromium (Cr)	2.8E0 lb/TBtu or 3.0E-2 lb/GWh	
	Cobalt (Co)	8.0E-1 lb/TBtu or 8.0E-3 lb/GWh	
	Lead (Pb)	1.2E0 lb/TBtu or 2.0E-2 lb/GWh	
	Manganese (Mn)	4.0E0 lb/TBtu or 5.0E-2 lb/GWh	
	Nickel (Ni)	3.5E0 lb/TBtu or 4.0E-2 lb/GWh	
	Selenium (Se)	5.0E0 lb/TBtu or 6.0E-2 lb/GWh	

TABLE 2 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR EXISTING EGUs—Continued

[As stated in § 63.9991, you must comply with the following applicable emission limits: [1]]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.,* specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
	b. Hydrogen chloride (HCl)	2.0E-3 lb/MMBtu or 2.0E-2 lb/MWh.	For Method 26A, collect a minimum of 0.75 dscm per run; for Method 26 at appendix A–8 to part 60 of this chapter, collect a minimum of 120 liters per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2)[4]	2.0E-1 lb/MMBtu or 1.5E0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	4.0E0 lb/TBtu or 4.0E-2 lb/GWh	LEE Testing for 30 days with a sampling period consistent with that given in section 5.2.1 of appendix A to this subpart per Method 30B run or Hg CEMS or sorbent trap monitoring system only.
3. IGCC unit	a. Filterable particulate matter (PM).	4.0E-2 lb/MMBtu or 4.0E-1 lb/MWh[2].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	6.0E-5 lb/MMBtu or 5.0E-1 lb/GWh.	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 2 dscm per run.
	Antimony (Sb)	1.4E0 lb/TBtu or 2.0E-2 lb/GWh	
	Arsenic (As)	1.5E0 lb/TBtu or 2.0E-2 lb/GWh	
	Beryllium (Be)	1.0E-1 lb/TBtu or 1.0E-3 lb/GWh	
	Cadmium (Cd)	1.5E-1 lb/TBtu or 2.0E-3 lb/GWh	
	Chromium (Cr)	2.9E0 lb/TBtu or 3.0E-2 lb/GWh	
	Cobalt (Co)	1.2E0 lb/TBtu or 2.0E-2 lb/GWh	
	Lead (Pb)	1.9E+2 lb/TBtu or 1.8E0 lb/GWh	
	Manganese (Mn)	2.5E0 lb/TBtu or 3.0E-2 lb/GWh	
	Nickel (Ni)	6.5E0 lb/TBtu or 7.0E-2 lb/GWh	
	Selenium (Se)	2.2E+1 lb/TBtu or 3.0E-1 lb/GWh	
	b. Hydrogen chloride (HCl)	5.0E-4 lb/MMBtu or 5.0E-3 lb/MWh.	For Method 26A, collect a minimum of 1 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 1 hour.
	c. Mercury (Hg)	2.5E0 lb/TBtu or 3.0E-2 lb/GWh	LEE Testing for 30 days with a sampling period consistent with that given in section 5.2.1 of appendix A to this subpart per Method 30B run or Hg CEMS or sorbent trap monitoring system only.
4. Liquid oil-fired unit—continental (excluding limited-use liquid oil-fired subcategory units).	a. Filterable particulate matter (PM).	3.0E-2 lb/MMBtu or 3.0E-1 lb/MWh[2].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total HAP metals	8.0E-4 lb/MMBtu or 8.0E-3 lb/MWh.	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 1 dscm per run.
	Antimony (Sb)	1.3E+1 lb/TBtu or 2.0E-1 lb/GWh	
	Arsenic (As)	2.8E0 lb/TBtu or 3.0E-2 lb/GWh	
	Beryllium (Be)	2.0E-1 lb/TBtu or 2.0E-3 lb/GWh	
	Cadmium (Cd)	3.0E-1 lb/TBtu or 2.0E-3 lb/GWh	
	Chromium (Cr)	5.5E0 lb/TBtu or 6.0E-2 lb/GWh	
	Cobalt (Co)	2.1E+1 lb/TBtu or 3.0E-1 lb/GWh	
	Lead (Pb)	8.1E0 lb/TBtu or 8.0E-2 lb/GWh	
	Manganese (Mn)	2.2E+1 lb/TBtu or 3.0E-1 lb/GWh	
	Nickel (Ni)	1.1E+2 lb/TBtu or 1.1E0 lb/GWh	

TABLE 2 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR EXISTING EGUs—Continued

[As stated in § 63.9991, you must comply with the following applicable emission limits: [1]]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.,* specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
	Selenium (Se)	3.3E0 lb/TBtu or 4.0E-2 lb/GWh	
	Mercury (Hg)	2.0E-1 lb/TBtu or 2.0E-3 lb/GWh	For Method 30B sample volume determination (Section 8.2.4), the estimated Hg concentration should nominally be < ½ the standard.
	b. Hydrogen chloride (HCl)	2.0E-3 lb/MMBtu or 1.0E-2 lb/MWh.	For Method 26A, collect a minimum of 1 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 1 hour.
	c. Hydrogen fluoride (HF)	4.0E-4 lb/MMBtu or 4.0E-3 lb/MWh.	For Method 26A, collect a minimum of 1 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 1 hour.
5. Liquid oil-fired unit—non-continental (excluding limited-use liquid oil-fired subcategory units).	a. Filterable particulate matter (PM).	3.0E-2 lb/MMBtu or 3.0E-1 lb/MWh[2].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total HAP metals	6.0E-4 lb/MMBtu or 7.0E-3 lb/MWh.	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 2 dscm per run.
	Antimony (Sb)	2.2E0 lb/TBtu or 2.0E-2 lb/GWh	
	Arsenic (As)	4.3E0 lb/TBtu or 8.0E-2 lb/GWh	
	Beryllium (Be)	6.0E-1 lb/TBtu or 3.0E-3 lb/GWh	
	Cadmium (Cd)	3.0E-1 lb/TBtu or 3.0E-3 lb/GWh	
	Chromium (Cr)	3.1E+1 lb/TBtu or 3.0E-1 lb/GWh	
	Cobalt (Co)	1.1E+2 lb/TBtu or 1.4E0 lb/GWh	
	Lead (Pb)	4.9E0 lb/TBtu or 8.0E-2 lb/GWh	
	Manganese (Mn)	2.0E+1 lb/TBtu or 3.0E-1 lb/GWh	
	Nickel (Ni)	4.7E+2 lb/TBtu or 4.1E0 lb/GWh	
	Selenium (Se)	9.8E0 lb/TBtu or 2.0E-1 lb/GWh	
	Mercury (Hg)	4.0E-2 lb/TBtu or 4.0E-4 lb/GWh	For Method 30B sample volume determination (Section 8.2.4), the estimated Hg concentration should nominally be < ½ the standard.
	b. Hydrogen chloride (HCl)	2.0E-4 lb/MMBtu or 2.0E-3 lb/MWh.	For Method 26A, collect a minimum of 1 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 2 hours.
	c. Hydrogen fluoride (HF)	6.0E-5 lb/MMBtu or 5.0E-4 lb/MWh.	For Method 26A, collect a minimum of 3 dscm per run. For ASTM D6348–03[3] or Method 320, sample for a minimum of 2 hours.
6. Solid oil-derived fuel-fired unit	a. Filterable particulate matter (PM).	8.0E-3 lb/MMBtu or 9.0E-2 lb/MWh[2].	Collect a minimum of 1 dscm per run.
	OR	OR	
	Total non-Hg HAP metals	4.0E-5 lb/MMBtu or 6.0E-1 lb/GWh.	Collect a minimum of 1 dscm per run.
	OR	OR	
	Individual HAP metals:		Collect a minimum of 3 dscm per run.
	Antimony (Sb)	8.0E-1 lb/TBtu or 7.0E-3 lb/GWh	
	Arsenic (As)	3.0E-1 lb/TBtu or 5.0E-3 lb/GWh	
	Beryllium (Be)	6.0E-2 lb/TBtu or 5.0E-4 lb/GWh	

TABLE 2 TO SUBPART UUUUU OF PART 63—EMISSION LIMITS FOR EXISTING EGUs—Continued

[As stated in § 63.9991, you must comply with the following applicable emission limits: [1]]

If your EGU is in this subcategory . . .	For the following pollutants . . .	You must meet the following emission limits and work practice standards . . .	Using these requirements, as appropriate (*e.g.*, specified sampling volume or test run duration) and limitations with the test methods in Table 5 to this Subpart . . .
	Cadmium (Cd)	3.0E-1 lb/TBtu or 4.0E-3 lb/GWh	
	Chromium (Cr)	8.0E-1 lb/TBtu or 2.0E-2 lb/GWh	
	Cobalt (Co)	1.1E0 lb/TBtu or 2.0E-2 lb/GWh	
	Lead (Pb)	8.0E-1 lb/TBtu or 2.0E-2 lb/GWh	
	Manganese (Mn)	2.3E0 lb/TBtu or 4.0E-2 lb/GWh	
	Nickel (Ni)	9.0E0 lb/TBtu or 2.0E-1 lb/GWh	
	Selenium (Se)	1.2E0 lb/Tbtu or 2.0E-2 lb/GWh	
	b. Hydrogen chloride (HCl)	5.0E-3 lb/MMBtu or 8.0E-2 lb/MWh.	For Method 26A, collect a minimum of 0.75 dscm per run; for Method 26, collect a minimum of 120 liters per run. For ASTM D6348–03 [3] or Method 320, sample for a minimum of 1 hour.
	OR		
	Sulfur dioxide (SO_2) [4]	3.0E-1 lb/MMBtu or 2.0E0 lb/MWh	SO_2 CEMS.
	c. Mercury (Hg)	2.0E-1 lb/TBtu or 2.0E-3 lb/GWh	LEE Testing for 30 days with a sampling period consistent with that given in section 5.2.1 of appendix A to this subpart per Method 30B run or Hg CEMS or sorbent trap monitoring system only.

[1] For LEE emissions testing for total PM, total HAP metals, individual HAP metals, HCl, and HF, the required minimum sampling volume must be increased nominally by a factor of two.

[2] Gross output.

[3] Incorporated by reference, see § 63.14.

[4] You may not use the alternate SO_2 limit if your EGU does not have some form of FGD system and SO_2 CEMS installed.

■ 23. Revise Table 3 to subpart UUUUU of part 63 to read as follows:

TABLE 3 TO SUBPART UUUUU OF PART 63—WORK PRACTICE STANDARDS

[As stated in § 63.9991, you must comply with the following applicable work practice standards:]

If your EGU is . . .	You must meet the following . . .
1. An existing EGU	Conduct a tune-up of the EGU burner and combustion controls at least each 36 calendar months, or each 48 calendar months if neural network combustion optimization software is employed, as specified in § 63.10021(e).
2. A new or reconstructed EGU.	Conduct a tune-up of the EGU burner and combustion controls at least each 36 calendar months, or each 48 calendar months if neural network combustion optimization software is employed, as specified in § 63.10021(e).
3. A coal-fired, liquid oil-fired (excluding limited-use liquid oil-fired subcategory units), or solid oil-derived fuel-fired EGU during startup.	a. You have the option of complying using either of the following work practice standards: (1) If you choose to comply using paragraph (1) of the definition of "startup" in § 63.10042, you must operate all CMS during startup. Startup means either the first-ever firing of fuel in a boiler for the purpose of producing electricity, or the firing of fuel in a boiler after a shutdown event for any purpose. Startup ends when any of the steam from the boiler is used to generate electricity for sale over the grid or for any other purpose (including on site use). For startup of a unit, you must use clean fuels as defined in § 63.10042 for ignition. Once you convert to firing coal, residual oil, or solid oil-derived fuel, you must engage all of the applicable control technologies except dry scrubber and SCR. You must start your dry scrubber and SCR systems, if present, appropriately to comply with relevant standards applicable during normal operation. You must comply with all applicable emissions limits at all times except for periods that meet the applicable definitions of startup and shutdown in this subpart. You must keep records during startup periods. You must provide reports concerning activities and startup periods, as specified in § 63.10011(g) and § 63.10021(h) and (i). (2) If you choose to comply using paragraph (2) of the definition of "startup" in § 63.10042, you must operate all CMS during startup. You must also collect appropriate data, and you must calculate the pollutant emission rate for each hour of startup. For startup of an EGU, you must use one or a combination of the clean fuels defined in § 63.10042 to the maximum extent possible, taking into account considerations such as boiler or control device integrity, throughout the startup period. You must have sufficient clean fuel capacity to engage and operate your PM control device within one hour of adding coal, residual oil, or solid oil-derived fuel to the unit. You must meet the startup period work practice requirements as identified in § 63.10020(e). Once you start firing coal, residual oil, or solid oil-derived fuel, you must vent emissions to the main stack(s). You must comply with the applicable emission limits beginning with the hour after startup ends. You must engage and operate your particulate matter control(s) within 1 hour of first firing of coal, residual oil, or solid oil-derived fuel.

TABLE 3 TO SUBPART UUUUU OF PART 63—WORK PRACTICE STANDARDS—Continued

[As stated in § 63.9991, you must comply with the following applicable work practice standards:]

If your EGU is . . .	You must meet the following . . .
	You must start all other applicable control devices as expeditiously as possible, considering safety and manufacturer/supplier recommendations, but, in any case, when necessary to comply with other standards made applicable to the EGU by a permit limit or a rule other than this Subpart that require operation of the control devices. b. Relative to the syngas not fired in the combustion turbine of an IGCC EGU during startup, you must either: (1) Flare the syngas, or (2) route the syngas to duct burners, which may need to be installed, and route the flue gas from the duct burners to the heat recovery steam generator. c. If you choose to use just one set of sorbent traps to demonstrate compliance with the applicable Hg emission limit, you must comply with the limit at all times; otherwise, you must comply with the applicable emission limit at all times except for startup and shutdown periods. d. You must collect monitoring data during startup periods, as specified in § 63.10020(a) and (e). You must keep records during startup periods, as provided in §§ 63.10032 and 63.10021(h). You must provide reports concerning activities and startup periods, as specified in §§ 63.10011(g), 63.10021(i), and 63.10031.
4. A coal-fired, liquid oil-fired (excluding limited-use liquid oil-fired subcategory units), or solid oil-derived fuel-fired EGU during shutdown.	You must operate all CMS during shutdown. You must also collect appropriate data, and you must calculate the pollutant emission rate for each hour of shutdown for those pollutants for which a CMS is used. While firing coal, residual oil, or solid oil-derived fuel during shutdown, you must vent emissions to the main stack(s) and operate all applicable control devices and continue to operate those control devices after the cessation of coal, residual oil, or solid oil-derived fuel being fed into the EGU and for as long as possible thereafter considering operational and safety concerns. In any case, you must operate your controls when necessary to comply with other standards made applicable to the EGU by a permit limit or a rule other than this Subpart and that require operation of the control devices. If, in addition to the fuel used prior to initiation of shutdown, another fuel must be used to support the shutdown process, that additional fuel must be one or a combination of the clean fuels defined in § 63.10042 and must be used to the maximum extent possible, taking into account considerations such as not compromising boiler or control device integrity. Relative to the syngas not fired in the combustion turbine of an IGCC EGU during shutdown, you must either: (1) Flare the syngas, or (2) route the syngas to duct burners, which may need to be installed, and route the flue gas from the duct burners to the heat recovery steam generator. You must comply with all applicable emission limits at all times except during startup periods and shutdown periods at which time you must meet this work practice. You must collect monitoring data during shutdown periods, as specified in § 63.10020(a). You must keep records during shutdown periods, as provided in §§ 63.10032 and 63.10021(h). Any fraction of an hour in which shutdown occurs constitutes a full hour of shutdown. You must provide reports concerning activities and shutdown periods, as specified in §§ 63.10011(g), 63.10021(i), and 63.10031.

■ 24. Revise Table 4 to subpart UUUUU of part 63 to read as follows:

TABLE 4 TO SUBPART UUUUU OF PART 63 — OPERATING LIMITS FOR EGUs

[As stated in § 63.9991, you must comply with the applicable operating limits:]

If you demonstrate compliance using . . .	You must meet these operating limits . . .
PM CPMS	Maintain the 30-boiler operating day rolling average PM CPMS output determined in accordance with the requirements of § 63.10023(b)(2) and obtained during the most recent performance test run demonstrating compliance with the filterable PM, total non-mercury HAP metals (total HAP metals, for liquid oil-fired units), or individual non-mercury HAP metals (individual HAP metals including Hg, for liquid oil-fired units) emissions limitation(s).

■ 25. Revise Table 5 to subpart UUUUU of part 63 to read as follows:

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS

[As stated in § 63.10007, you must comply with the following requirements for performance testing for existing, new or reconstructed affected sources: [1]]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . . [2]
1. Filterable Particulate matter (PM).	Emissions Testing	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS—Continued

[As stated in § 63.10007, you must comply with the following requirements for performance testing for existing, new or reconstructed affected sources: [1]]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . .[2]
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the filterable PM concentration.	Method 5 at appendix A–3 to part 60 of this chapter. For positive pressure fabric filters, Method 5D at appendix A–3 to part 60 of this chapter for filterable PM emissions. Note that the Method 5 front half temperature shall be 160° ± 14° C (320° ± 25° F).
		f. Convert emissions concentration to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR.	
	PM CEMS	a. Install, certify, operate, and maintain the PM CEMS.	Performance Specification 11 at appendix B to part 60 of this chapter and Procedure 2 at appendix F to part 60 of this chapter.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
2. Total or individual non-Hg HAP metals.	Emissions Testing	a. Select sampling ports location and the number of traverse points..	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the HAP metals emissions concentrations and determine each individual HAP metals emissions concentration, as well as the total filterable HAP metals emissions concentration and total HAP metals emissions concentration.	Method 29 at appendix A–8 to part 60 of this chapter. For liquid oil-fired units, Hg is included in HAP metals and you may use Method 29, Method 30B at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately. When using Method 29, report metals matrix spike and recovery levels.
		f. Convert emissions concentrations (individual HAP metals, total filterable HAP metals, and total HAP metals) to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
3. Hydrogen chloride (HCl) and hydrogen fluoride (HF).	Emissions Testing	a. Select sampling ports location and the number of traverse points..	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.

TABLE 5 TO SUBPART UUUUU OF PART 63—PERFORMANCE TESTING REQUIREMENTS—Continued

[As stated in § 63.10007, you must comply with the following requirements for performance testing for existing, new or reconstructed affected sources: [1]]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . .[2]
		e. Measure the HCl and HF emissions concentrations.	Method 26 or Method 26A at appendix A–8 to part 60 of this chapter or Method 320 at appendix A to part 63 of this chapter or ASTM 6348–03[3] with (1) the following conditions when using ASTM D6348–03: (A) The test plan preparation and implementation in the Annexes to ASTM D6348–03, Sections A1 through A8 are mandatory; (B) For ASTM D6348–03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (see Equation A5.5); (C) For the ASTM D6348–03 test data to be acceptable for a target analyte, %R must be 70% ≥ R ≤ 130%; and

3.e.1(D) The %R value for each compound must be reported in the test report and all field measurements corrected with the calculated %R value for that compound using the following equation:

$$\text{Reported Result} = \frac{(\text{Measured Concentration in Stack})}{\%\text{R}}\, x\, 100$$

and

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
			(2) spiking levels nominally no greater than two times the level corresponding to the applicable emission limit. Method 26A must be used if there are entrained water droplets in the exhaust stream.
		f. Convert emissions concentration to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR.	
	HCl and/or HF CEMS	a. Install, certify, operate, and maintain the HCl or HF CEMS.	Appendix B of this subpart.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
4. Mercury (Hg)	Emissions Testing	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the Hg emission concentration.	Method 30B at appendix A–8 to part 60 of this chapter, ASTM D6784,[3] or Method 29 at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately.
		f. Convert emissions concentration to lb/TBtu or lb/GWh emission rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR.	
	Hg CEMS	a. Install, certify, operate, and maintain the CEMS.	Sections 3.2.1 and 5.1 of appendix A of this subpart.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Section 6 of appendix A to this subpart.
	OR	OR.	
	Sorbent trap monitoring system.	a. Install, certify, operate, and maintain the sorbent trap monitoring system.	Sections 3.2.2 and 5.2 of appendix A to this subpart.
		b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Section 6 of appendix A to this subpart.
	OR	OR.	
	LEE testing	a. Select sampling ports location and the number of traverse points.	Single point located at the 10% centroidal area of the duct at a port location per Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G, or 2H at appendix A–1 or A–2 to part 60 of this chapter or flow monitoring system certified per appendix A of this subpart.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981,[3] or diluent gas monitoring systems certified according to part 75 of this chapter.
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter, or moisture monitoring systems certified according to part 75 of this chapter.
		e. Measure the Hg emission concentration.	Method 30B at appendix A–8 to part 60 of this chapter; perform a 30 operating day test, with a maximum of 10 operating days per run (*i.e.,* per pair of sorbent traps) or sorbent trap monitoring system or Hg CEMS certified per appendix A of this subpart.
		f. Convert emissions concentrations from the LEE test to lb/TBtu or lb/GWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
		g. Convert average lb/TBtu or lb/GWh Hg emission rate to lb/year, if you are attempting to meet the 29.0 lb/year threshold.	Potential maximum annual heat input in TBtu or potential maximum electricity generated in GWh.

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
5. Sulfur dioxide (SO_2)	SO_2 CEMS	a. Install, certify, operate, and maintain the CEMS.	Part 75 of this chapter and § 63.10010(a) and (f).
		b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).

[1] Regarding emissions data collected during periods of startup or shutdown, see §§ 63.10020(b) and (c) and 63.10021(h).
[2] See Tables 1 and 2 to this subpart for required sample volumes and/or sampling run times.
[3] Incorporated by reference, see § 63.14.

■ 26. Revise Table 6 to subpart UUUUU of part 63 to read as follows:

TABLE 6 TO SUBPART UUUUU OF PART 63—ESTABLISHING PM CPMS OPERATING LIMITS

[As stated in § 63.10007, you must comply with the following requirements for establishing operating limits:]

If you have an applicable emission limit for . . .	And you choose to establish PM CPMS operating limits, you must . . .	And . . .	Using . . .	According to the following procedures . . .
Filterable Particulate matter (PM), total non-mercury HAP metals, individual non-mercury HAP metals, total HAP metals, or individual HAP metals for an EGU.	Install, certify, maintain, and operate a PM CPMS for monitoring emissions discharged to the atmosphere according to § 63.10010(h)(1).	Establish a site-specific operating limit in units of PM CPMS output signal (*e.g.,* milliamps, mg/acm, or other raw signal).	Data from the PM CPMS and the PM or HAP metals performance tests.	1. Collect PM CPMS output data during the entire period of the performance tests. 2. Record the average hourly PM CPMS output for each test run in the performance test. 3. Determine the PM CPMS operating limit in accordance with the requirements of § 63.10023(b)(2) from data obtained during the performance test demonstrating compliance with the filterable PM or HAP metals emissions limitations.

■ 27. Revise Table 8 to subpart UUUUU of part 63 to read as follows:

TABLE 8 TO SUBPART UUUUU OF PART 63—REPORTING REQUIREMENTS

[As stated in § 63.10031, you must comply with the following requirements:]

You must submit a	The report must contain . . .	You must submit the report . . .
1. Compliance report.	a. Information required in § 63.10031(c)(1) through (9); and b. If there are no deviations from any emission limitation (emission limit and operating limit) that applies to you and there are no deviations from the requirements for work practice standards in Table 3 to this subpart that apply to you, a statement that there were no deviations from the emission limitations and work practice standards during the reporting period. If there were no periods during which the CMSs, including continuous emissions monitoring system, and operating parameter monitoring systems, were out-of-control as specified in § 63.8(c)(7), a statement that there were no periods during which the CMSs were out-of-control during the reporting period; and. c. If you have a deviation from any emission limitation (emission limit and operating limit) or work practice standard during the reporting period, the report must contain the information in § 63.10031(d). If there were periods during which the CMSs, including continuous emissions monitoring systems and continuous parameter monitoring systems, were out-of-control, as specified in § 63.8(c)(7), the report must contain the information in § 63.10031(e)..	Semiannually according to the requirements in § 63.10031(b).

■ 28. Revise Table 9 to subpart UUUUU of part 63 to read as follows:

TABLE 9 TO SUBPART UUUUU OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART UUUUU

[As stated in § 63.10040, you must comply with the applicable General Provisions according to the following:]

Citation	Subject	Applies to subpart UUUUU
§ 63.1	Applicability	Yes.
§ 63.2	Definitions	Yes. Additional terms defined in § 63.10042.
§ 63.3	Units and Abbreviations	Yes.
§ 63.4	Prohibited Activities and Circumvention	Yes.
§ 63.5	Preconstruction Review and Notification Requirements.	Yes.
§ 63.6(a), (b)(1) through (5), (b)(7), (c), (f)(2) and (3), (h)(2) through (9), (i), (j).	Compliance with Standards and Maintenance Requirements.	Yes.
§ 63.6(e)(1)(i)	General Duty to minimize emissions	No. See § 63.10000(b) for general duty requirement.
§ 63.6(e)(1)(ii)	Requirement to correct malfunctions ASAP	No.
§ 63.6(e)(3)	SSM Plan requirements	No.
§ 63.6(f)(1)	SSM exemption	No.
§ 63.6(h)(1)	SSM exemption	No.
§ 63.6(g)	Compliance with Standards and Maintenance Requirements, Use of an alternative non-opacity emission standard.	Yes. See §§ 63.10011(g)(4) and 63.10021(h)(4) for additional requirements.
§ 63.7(e)(1)	Performance testing	No. See § 63.10007.
§ 63.8	Monitoring Requirements	Yes.
§ 63.8(c)(1)(i)	General duty to minimize emissions and CMS operation.	No. See § 63.10000(b) for general duty requirement.
§ 63.8(c)(1)(iii)	Requirement to develop SSM Plan for CMS	No.
§ 63.8(d)(3)	Written procedures for CMS	Yes, except for last sentence, which refers to an SSM plan. SSM plans are not required.
§ 63.9	Notification Requirements	Yes, except (1) for the 60-day notification prior to conducting a performance test in § 63.9(e); instead use a 30-day notification period per § 63.10030(d), (2) the notification of the CMS performance evaluation in § 63.9(g)(1) is limited to RATAs, and (3) the information required per § 63.9(h)(2)(i); instead provide the information required per § 63.10030(e)(1) through (e)(6) and (e)(8).
§ 63.10(a), (b)(1), (c), (d)(1) and (2), (e), and (f)	Recordkeeping and Reporting Requirements	Yes, except for the requirements to submit written reports under § 63.10(e)(3)(v).
§ 63.10(b)(2)(i)	Recordkeeping of occurrence and duration of startups and shutdowns.	No.
§ 63.10(b)(2)(ii)	Recordkeeping of malfunctions	No. See § 63.10001 for recordkeeping of (1) occurrence and duration and (2) actions taken during malfunction.
§ 63.10(b)(2)(iii)	Maintenance records	Yes.
§ 63.10(b)(2)(iv)	Actions taken to minimize emissions during SSM.	No.
§ 63.10(b)(2)(v)	Actions taken to minimize emissions during SSM.	No.
§ 63.10(b)(2)(vi)	Recordkeeping for CMS malfunctions	Yes.
§ 63.10(b)(2)(vii) through (ix)	Other CMS requirements	Yes.
§ 63.10(b)(3) and (d)(3) through (5)		No.
§ 63.10(c)(7)	Additional recordkeeping requirements for CMS—identifying exceedances and excess emissions.	Yes.
§ 63.10(c)(8)	Additional recordkeeping requirements for CMS—identifying exceedances and excess emissions.	Yes.
§ 63.10(c)(10)	Recording nature and cause of malfunctions	No. See § 63.10032(g) and (h) for malfunctions recordkeeping requirements.
§ 63.10(c)(11)	Recording corrective actions	No. See § 63.10032(g) and (h) for malfunctions recordkeeping requirements.
§ 63.10(c)(15)	Use of SSM Plan	No.
§ 63.10(d)(5)	SSM reports	No. See § 63.10021(h) and (i) for malfunction reporting requirements.
§ 63.11	Control Device Requirements	No.
§ 63.12	State Authority and Delegation	Yes.
§§ 63.13 through 63.16	Addresses, Incorporation by Reference, Availability of Information, Performance Track Provisions.	Yes.

TABLE 9 TO SUBPART UUUUU OF PART 63—APPLICABILITY OF GENERAL PROVISIONS TO SUBPART UUUUU—Continued

[As stated in § 63.10040, you must comply with the applicable General Provisions according to the following:]

Citation	Subject	Applies to subpart UUUUU
§§ 63.1(a)(5),(a)(7) through (9), (b)(2), (c)(3) and (4), (d), 63.6(b)(6), (c)(3) and (4), (d), (e)(2), (e)(3)(ii), (h)(3), (h)(5)(iv), 63.8(a)(3), 63.9(b)(3), (h)(4), 63.10(c)(2) through (4), (c)(9)..	Reserved	No.

■ 29. Appendix A to subpart UUUUU of part 63 is amended by revising paragraphs 3.2.1.2.1, 4.1.1.1, and 4.1.1.3, table A–1, paragraphs 4.1.1.5, 4.1.1.5.2, 5.1.2.1, and 5.1.2.3, table A–2, and paragraphs 5.2.1, 6.2.2.3, and 7.1.8.5 and adding paragraph 7.1.2.6 to read as follows:

Appendix A to Subpart UUUUU of Part 63—Hg Monitoring Provisions

* * * * *

3. Mercury Emissions Measurement Methods

* * * * *

3.2.1.2.1 *NIST Traceability.* Only NIST-certified or NIST-traceable calibration gas standards and reagents (as defined in paragraphs 3.1.4 and 3.1.5 of this appendix), and including, but not limited to, Hg gas generators and Hg gas cylinders, shall be used for the tests and procedures required under this subpart. Calibration gases with known concentrations of Hg^0 and $HgCl_2$ are required. Special reagents and equipment may be needed to prepare the Hg^0 and $HgCl_2$ gas standards (*e.g.,* NIST-traceable solutions of $HgCl_2$ and gas generators equipped with mass flow controllers).

* * * * *

4. Certification and Recertification Requirements

* * * * *

4.1.1.1 *7-Day Calibration Error Test.* Perform the 7-day calibration error test on 7 consecutive source operating days, using a zero-level gas and either a high-level or a mid-level calibration gas standard (as defined in paragraphs 3.1.8, 3.1.10, and 3.1.11 of this appendix). Use a NIST-traceable elemental Hg gas standard (as defined in paragraphs 3.1.4 of this appendix) for the test. If your Hg CEMS lacks an integrated elemental Hg gas generator, you may continue to use NIST-traceable oxidized Hg gases for the 7-day calibration error test (or the daily calibration error check) until such time as NIST-traceable compressed elemental Hg gas standards, at appropriate concentration levels, are available from gas vendors. If moisture is added to the calibration gas, the dilution effect of the moisture and/or chlorine addition on the calibration gas concentration must be accounted for in an appropriate manner. Operate the Hg CEMS in its normal sampling mode during the test. The calibrations should be approximately 24 hours apart, unless the 7-day test is performed over non-consecutive calendar days. On each day of the test, inject the zero-level and upscale gases in sequence and record the analyzer responses. Pass the calibration gas through all filters, scrubbers, conditioners, and other monitor components used during normal sampling, and through as much of the sampling probe as is practical. Do not make any manual adjustments to the monitor (*i.e.,* resetting the calibration) until after taking measurements at both the zero and upscale concentration levels. If automatic adjustments are made following both injections, conduct the calibration error test such that the magnitude of the adjustments can be determined, and use only the unadjusted analyzer responses in the calculations. Calculate the calibration error (CE) on each day of the test, as described in Table A–1 of this appendix. The CE on each day of the test must either meet the main performance specification or the alternative specification in Table A–1 of this appendix.

* * * * *

4.1.1.3 *Three-Level System Integrity Check.* Perform the 3-level system integrity check using low, mid, and high-level calibration gas concentrations generated by a NIST-traceable source of oxidized Hg. If your Hg CEMS lacks an integrated elemental Hg gas generator, you may continue to use NIST-traceable oxidized Hg gases for the 7-day calibration error test (or the daily calibration error check) until such time as NIST-traceable compressed elemental Hg gas standards, at appropriate concentration levels, are available from gas vendors. Follow the same basic procedure as for the linearity check. If moisture and/or chlorine is added to the calibration gas, the dilution effect of the moisture and/or chlorine addition on the calibration gas concentration must be accounted for in an appropriate manner. Calculate the system integrity error (SIE), as described in Table A–1 of this appendix. The SIE must either meet the main performance specification or the alternative specification in Table A–1 of this appendix.

TABLE A–1—REQUIRED CERTIFICATION TESTS AND PERFORMANCE SPECIFICATIONS FOR H_g CEMS

For this required certification test . . .	The main performance specification[1] is . . .	The alternate performance specification[1] is . . .	And the conditions of the alternate specification are . . .
7-day calibration error test[2 6]	$\|R - A\| \leq 5.0\%$ of span value, for both the zero and upscale gases, on each of the 7 days..	$\|R - A\| \leq 1.0$ μg/scm	The alternate specification may be used on any day of the test.
Linearity check[3 6]	$\|R - A_{avg}\| \leq 10.0\%$ of the reference gas concentration at each calibration gas level (low, mid, or high)..	$\|R - A_{avg}\| \leq 0.8$ μg/scm	The alternate specification may be used at any gas level.
3-level system integrity check[4]	$\|R - A_{avg}\| \leq 10.0\%$ of the reference gas concentration at each calibration gas level..	$\|R - A_{avg}\| \leq 0.8$ μg/scm	The alternate specification may be used at any gas level.

TABLE A–1—REQUIRED CERTIFICATION TESTS AND PERFORMANCE SPECIFICATIONS FOR H_g CEMS—Continued

For this required certification test . . .	The main performance specification[1] is . . .	The alternate performance specification[1] is . . .	And the conditions of the alternate specification are . . .
RATA	20.0% RA	$\lvert RM_{avg} - C_{avg}\rvert + \lvert CC\rvert \le 0.5$ µg/scm[7].	$RM_{avg} < 2.5$µg/scm
Cycle time test[5]	15 minutes where the stability criteria are readings change by < 2.0% of span *or* by ≤ 0.5 µg/scm, for 2 minutes..		

[1] Note that $\lvert R - A\rvert$ is the absolute value of the difference between the reference gas value and the analyzer reading. $\lvert R - A_{avg}\rvert$ is the absolute value of the difference between the reference gas concentration and the average of the analyzer responses, at a particular gas level.

[2] Use elemental Hg standards; a mid-level or high-level upscale gas may be used.

[3] Use elemental Hg standards.

[4] Use oxidized Hg standards.

[5] Use elemental Hg standards; a high-level upscale gas must be used. The cycle time test is not required for Hg CEMS that use integrated batch sampling; however, those monitoring systems must be capable of recording at least one Hg concentration reading every 15 minutes.

[6] If your Hg CEMS lacks an integrated elemental Hg gas generator, you may continue to use NIST-traceable oxidized Hg gases until such time as NIST-traceable compressed elemental Hg gas standards, at appropriate concentration levels, are available from gas vendors.

[7] Note that $\lvert RM_{avg} - C_{avg}\rvert$ is the absolute difference between the mean reference method value and the mean CEMS value from the RATA; CC is the confidence coefficient from Equation 2–5 of Performance Specification 2 in appendix B to part 60 of this chapter.

* * * * *

4.1.1.5 *Relative Accuracy Test Audit (RATA).* Perform the RATA of the Hg CEMS at normal load. Acceptable Hg reference methods for the RATA include ASTM D6784–02 (Reapproved 2008), "Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method)" (incorporated by reference, see § 63.14) and Methods 29, 30A, and 30B in appendix A–8 to part 60 of this chapter. When Method 29 or ASTM D6784–02 is used, paired sampling trains are required and the filterable portion of the sample need not be included when making comparisons to the Hg CEMS results for purposes of a RATA. To validate a Method 29 or ASTM D6784–02 test run, calculate the relative deviation (RD) using Equation A–1 of this section, and assess the results as follows to validate the run. The RD must not exceed 10 percent, when the average Hg concentration is greater than 1.0 µg/dscm. If the RD specification is met, the results of the two samples shall be averaged arithmetically.

$$RD = \frac{|C_a - C_b|}{C_a + C_b} \times 100 \quad (Eq.\ A-1)$$

Where:

RD = Relative Deviation between the Hg concentrations of samples "a" and "b" (percent),

C_a = Hg concentration of Hg sample "a" (µg/dscm), and

C_b = Hg concentration of Hg sample "b" (µg/dscm).

* * * * *

4.1.1.5.2 *Calculation of RATA Results.* Calculate the relative accuracy (RA) of the monitoring system, on a µg/scm basis, as described in section 12 of Performance Specification (PS) 2 in appendix B to part 60 of this chapter (see Equations 2–3 through 2–6 of PS2) including the option to substitute the emission limit value (in this case the equivalent concentration) in the denominator of Equation 2–6 in place of the average RM value when the average emissions for the test are less than 50 percent of the applicable emissions limit. For purposes of calculating the relative accuracy, ensure that the reference method and monitoring system data are on a consistent basis, either wet or dry. The CEMS must either meet the main performance specification or the alternative specification in Table A–1 of this appendix.

* * * * *

5. Ongoing Quality Assurance (QA) and Data Validation

* * * * *

5.1.2.1 Calibration error tests of the Hg CEMS are required daily, except during unit outages. Use a NIST-traceable elemental Hg gas standard for these calibrations. If your Hg CEMS lacks an integrated elemental Hg gas generator, you may continue to use NIST-traceable oxidized Hg gases for the 7-day calibration error test (or the daily calibration error check) until such time as NIST-traceable compressed elemental Hg gas standards, at appropriate concentration levels, are available from gas vendors. Both a zero-level gas and either a mid-level or high-level gas are required for these calibrations.

* * * * *

5.1.2.3 Perform a single-level system integrity check weekly, *i.e.*, once every 7 operating days (see the third column in Table A–2 of this appendix).

* * * * *

TABLE A–2—ON-GOING QA TEST REQUIREMENTS FOR H_g CEMS

Perform this type of QA test . . .	At this frequency . . .	With these qualifications and exceptions . . .	Acceptance criteria . . .
Calibration error test [5]	Daily	• Use either a mid- or high-level gas. • Use elemental Hg • Calibrations are not required when the unit is not in operation..	$\|R - A\| \leq 5.0\%$ of span value *or* $\|R - A\| \leq 1.0$ μg/scm.
Single-level system integrity check.	Weekly [1]	• Use oxidized Hg—either mid- or high-level.	$\|R - A_{avg}\| \leq 10.0\%$ of the reference gas value *or* $\|R - A_{avg}\| \leq 0.8$ μg/scm.
Linearity check *or* 3-level system integrity check.	Quarterly [3]	• Required in each "QA operating quarter" [2] and no less than once every 4 calendar quarters. • 168 operating hour grace period available. • Use elemental Hg for linearity check. • Use oxidized Hg for system integrity check.	$\|R - A_{avg}\| \leq 10.0\%$ of the reference gas value, at each calibration gas level *or* $\|R - A_{avg}\| \leq 0.8$ μg/scm.
RATA	Annual [4]	• Test deadline may be extended for "non-QA operating quarters," up to a maximum of 8 quarters from the quarter of the previous test.. • 720 operating hour grace period available.	≤20.0% RA when $C_{avg} \geq 2.5$ μg/scm *or* $\|RM_{avg} - C_{avg}\| + \|CC\| \leq 0.5$ μgμ/scm, if $RM_{avg} < 2.5$ μg/scm.

[1] "Weekly" means once every 7 operating days.

[2] A "QA operating quarter" is a calendar quarter with at least 168 unit or stack operating hours.

[3] "Quarterly" means once every QA operating quarter.

[4] "Annual" means once every four QA operating quarters.

[5] If your Hg CEMS lacks an integrated elemental Hg gas generator, you may continue to use NIST-traceable oxidized Hg gases until such time as NIST-traceable compressed elemental Hg gas standards, at appropriate concentration levels, are available from gas vendors.

* * * * *

5.2.1 Each sorbent trap monitoring system shall be continuously operated and maintained in accordance with Performance Specification (PS) 12B in appendix B to part 60 of this chapter. The QA/QC criteria for routine operation of the system are summarized in Table 12B–1 of PS 12B. Each pair of sorbent traps may be used to sample the stack gas for up to 15 operating days.

* * * * *

6. Data Reductions and Calculations

* * * * *

6.2.2.3 The applicable gross output-based Hg emission rate limit in Table 1 or 2 to this subpart must be met on a 30- (or 90-) boiler operating day rolling average basis, except as otherwise provided in § 63.10009(a)(2). Use Equation A–5 of this appendix to calculate the Hg emission rate for each averaging period.

$$\bar{E}_o = \frac{\sum_{h=1}^{n} E_{ho}}{n} \quad (Eq.\ A-5)$$

Where:

$\bar{E}_o$ = Hg emission rate for the averaging period (lb/GWh),

E_{ho} = Gross output-based hourly Hg emission rate for unit or stack sampling hour "h" in the averaging period, from Equation A–4 of this appendix (lb/GWh), and

n = Number of unit or stack operating hours in the averaging period in which valid data were obtained for all parameters. **(Note: Do *not* include non-operating hours with zero emission rates in the average).**

* * * * *

7. Recordkeeping and Reporting

* * * * *

7.1.2.6 The EGUs that constitute an emissions averaging group.

* * * * *

7.1.8.5 If applicable, a code to indicate that the default gross output (as defined in § 63.10042) was used to calculate the Hg emission rate.

* * * * *

■ 30. Appendix B to subpart UUUUU of part 63 is amended by:

■ a. Revising paragraphs 2.1 and 2.3;

■ b. Adding paragraphs 2.3.1 and 2.3.2;

■ c. Revising paragraphs 3.1 and 3.2 and adding paragraph 3.3;

■ d. Adding introductory text to section 5;

■ e. Revising paragraphs 5.1, 5.1.2, 5.2, and 5.3;

■ f. Adding paragraphs 5.4, 5.4.1, 5.4.2, 5.4.2.1, 5.4.2.2, 5.4.2.2.1, 5.4.2.2.2, 5.4.2.3, 5.4.2.3.1, 5.4.2.3.2, 5.4.2.3.3, and 5.4.3; and

■ g. Revising section 8 introductory text and paragraph 9.3.2.

The revisions and additions read as follows:

Appendix B to Subpart UUUUU of Part 63—HCl and HF Monitoring Provisions

* * * * *

2. Monitoring of HCl and/or HF Emissions

2.1 *Monitoring System Installation Requirements.* Install HCl and/or HF CEMS and any additional monitoring systems needed to convert pollutant concentrations to units of the applicable emissions limit in accordance with § 63.10010(a) and either Performance Specification 15 (PS 15) of appendix B to part 60 of this chapter for extractive Fourier Transform Infrared Spectroscopy (FTIR) continuous emissions monitoring systems or Performance Specification 18 (PS 18) of appendix B to part 60 of this chapter for HCl CEMS.

* * * * *

2.3 *FTIR Monitoring System Equipment, Supplies, Definitions, and General Operation.* The following provisions apply:

2.3.1 PS 15, Sections 2.0, 3.0, 4.0, 5.0, 6.0, and 10.0 of appendix B to part 60 of this chapter; or

2.3.2 PS 18, Sections 3.0, 6.0, and 11.0 of appendix B to part 60 of this chapter.

3. Initial Certification Procedures

* * * * *

3.1 If you choose to follow PS 15 of appendix B to part 60 of this chapter, then your HCl and/or HF CEMS must be certified according to PS 15 using the procedures for gas auditing and comparison to a reference method (RM) as specified in sections 3.1.1 and 3.1.2 below.

* * * * *

3.2 If you choose to follow PS 18 of appendix B to part 60 of this chapter, then your HCl CEMS must be certified according to PS 18, sections 7.0, 8.0, 11.0, 12.0, and 13.0.

3.3 Any additional stack gas flow rate, diluent gas, and moisture monitoring system(s) needed to express pollutant concentrations in units of the applicable emissions limit must be certified according to part 75 of this chapter.

* * * * *

5. On-Going Quality Assurance Requirements

On-going QA test requirements for HCl and HF CEMS must be implemented as follows:

5.1 If you choose to follow Performance Specification 15 (PS 15) of appendix B to part 60 of this chapter, then the quality assurance/quality control procedures of PS 15 shall apply as set forth in sections 5.1.1 through 5.1.3 and 5.4.2 of this appendix.

* * * * *

5.1.2 On a quarterly basis, you must conduct a gas audit of the HCl and/or HF CEMS as described in section 3.1.1 of this appendix. For the purposes of this appendix, "quarterly" means once every "QA operating quarter" (as defined in section 3.1.20 of appendix A to this subpart). You have the option to use HCl gas in lieu of HF gas for conducting this audit on an HF CEMS. To the extent practicable, perform consecutive quarterly gas audits at least 30 days apart. The initial quarterly audit is due in the first QA operating quarter following the calendar quarter in which certification testing of the CEMS is successfully completed. Up to three consecutive exemptions from the quarterly audit requirement are allowed for "non-QA operating quarters" (*i.e.,* calendar quarters in which there are less than 168 unit or stack operating hours). However, no more than four consecutive calendar quarters may elapse without performing a gas audit, except as otherwise provided in section 5.4.2.2.1 of this appendix.

* * * * *

5.2 If you choose to follow Performance Specification PS 18 of appendix B to part 60 of this chapter, then the quality assurance/quality control procedures in Procedure 6 of appendix F to part 60 of this chapter shall apply. The quarterly and annual QA tests required under Procedure 6 shall be performed, respectively, at the frequencies specified in sections 5.1.2 and 5.1.3 of this appendix.

5.3 Stack gas flow rate, diluent gas, and moisture monitoring systems must meet the applicable on-going QA test requirements of part 75 of this chapter.

* * * * *

5.4 *Data Validation.*

5.4.1 *Out-of-Control Periods.* An HCl or HF CEMS that is used to provide data under this appendix is considered to be out-of-control, and data from the CEMS may not be reported as quality-assured, when any acceptance criteria for a required QA test is not met. The HCl or HF CEMS is also considered to be out-of-control when a required QA test is not performed on schedule or within an allotted grace period. To end an out-of-control period, the QA test that was either failed or not done on time must be performed and passed. Out-of-control periods are counted as hours of monitoring system downtime.

5.4.2 *Grace Periods.* For the purposes of this appendix, a "grace period" is defined as a specified number of unit or stack operating hours after the deadline for a required quality-assurance test of a continuous monitor has passed, in which the test may be performed and passed without loss of data.

5.4.2.1 For the monitoring systems described in section 5.3 of this appendix, a 168 unit or stack operating hour grace period is available for quarterly linearity checks, and a 720 unit or stack operating hour grace period is available for RATAs, as provided, respectively, in sections 2.2.4 and 2.3.3 of appendix B to part 75 of this chapter.

5.4.2.2 For the purposes of this appendix, if the deadline for a required gas audit/data accuracy assessment or RATA of an HCl CEMS cannot be met due to circumstances beyond the control of the owner or operator:

5.4.2.2.1 A 168 unit or stack operating hour grace period is available in which to perform the gas audit or other quarterly data accuracy assessment; or

5.4.2.2.2 A 720 unit or stack operating hour grace period is available in which to perform the RATA.

5.4.2.3 If a required QA test is performed during a grace period, the deadline for the next test shall be determined as follows:

5.4.2.3.1 For a gas audit or RATA of the monitoring systems described in sections 5.1 and 5.2 of this appendix, determine the deadline for the next gas audit or RATA (as applicable) in accordance with section 2.2.4(b) or 2.3.3(d) of appendix B to part 75 of this chapter; treat a gas audit in the same manner as a linearity check.

5.4.2.3.2 For the gas audit or other quarterly data accuracy assessment of an HCl or HF CEMS, the grace period test only satisfies the audit requirement for the calendar quarter in which the test was originally due. If the calendar quarter in which the grace period audit is performed is a QA operating quarter, an additional gas audit/data accuracy assessment is required for that quarter.

5.4.2.3.3 For the RATA of an HCl or HF CEMS, the next RATA is due within three QA operating quarters after the calendar quarter in which the grace period test is performed.

5.4.3 *Conditional Data Validation.* For recertification and diagnostic testing of the monitoring systems that are used to provide data under this appendix, the conditional data validation provisions in § 75.20(b)(3)(ii) through (ix) of this chapter may be used to avoid or minimize data loss. The allotted window of time to complete calibration tests and RATAs shall be as specified in § 75.20(b)(3)(iv) of this chapter; the allotted window of time to complete a quarterly gas audit or data accuracy assessment shall be the same as for a linearity check (*i.e.,* 168 unit or stack operating hours).

* * * * *

8. QA/QC Program Requirements

The owner or operator shall develop and implement a quality assurance/quality control (QA/QC) program for the HCl and/or HF CEMS that are used to provide data under this subpart. At a minimum, the program shall include a written plan that describes in detail (or that refers to separate documents containing) complete, step-by-step procedures and operations for the most important QA/QC activities. Electronic storage of the QA/QC plan is permissible, provided that the information can be made available in hard copy to auditors and inspectors. The QA/QC program requirements for the other monitoring systems described in section 5.3 of this appendix are specified in section 1 of appendix B to part 75 of this chapter.

* * * * *

9. Data Reduction and Calculations

* * * * *

9.3.2 For gross output-based emission rates, first calculate the HCl or HF mass emission rate (lb/h), using an equation that has the general form of Equation A–2 or A–3 in appendix A to this subpart (as applicable), replacing the value of K with 9.43×10^{-8} lb/scf-ppm (for HCl) or 5.18×10^{-8} (for HF) and defining C_h as the hourly average HCl or HF concentration in ppm. Then, divide the result by the hourly gross output (megawatts) to convert it to units of lb/MWh. If the gross output is zero during a startup or shutdown hour, use the default gross output (as defined in § 63.10042) to calculate the HCl or HF emission rate. The default gross output is not considered to be a substitute data value.

* * * * *

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Part V

The President

Proclamation 9415—National Donate Life Month, 2016
Proclamation 9416—National Public Health Week, 2016
Proclamation 9417—National Autism Awareness Day, 2016
Notice of April 4, 2016—Continuation of the National Emergency With Respect to Somalia

Federal Register
Vol. 81, No. 66
Wednesday, April 6, 2016

Presidential Documents

Title 3—

The President

Proclamation 9415 of April 1, 2016

National Donate Life Month, 2016

By the President of the United States of America

A Proclamation

By becoming an organ donor, one person can save the lives of up to eight people and improve the lives of dozens—mothers and daughters, fathers and sons, brothers and sisters—who are desperately in need of a transplant. During National Donate Life Month, we lift up the thousands of selfless individuals across America who are living or registered organ donors. And as we honor those who have saved lives in the past by donating organs, we recommit to supporting the researchers, innovators, advocates, and medical professionals working to reduce the number of people awaiting vital organ transplants.

A rising demand for organs exists without enough organs to meet it, making the urgency for those willing and able to donate even more critical and the need for innovation and support even more imperative. My Administration has striven to support donors and recipients and to expand the availability of organs for transplant. In 2010, the Department of Health and Human Services (HHS), building on efforts within the transplant community, launched a nationwide kidney exchange program to bring together pairs of kidney donors and recipients in an effort to increase the quality and quantity of kidney transplants. HHS has also made more financial support available to low-income living donors to help cover expenses like travel and lodging costs that are often incurred throughout the donation process. The Affordable Care Act offers greater security to living donors by prohibiting insurers from denying health coverage to someone with a preexisting condition—donating an organ may have previously been considered a preexisting condition and prevented individuals from obtaining the care they deserved after selflessly giving an organ to someone in need. And in 2013, I signed the bipartisan HOPE Act, paving the way for the first transplants in the United States between HIV-positive donors and recipients—and the first of these life-saving transplants took place earlier this year.

Anyone can indicate their desire to be a donor, regardless of age or medical history, and I encourage all Americans to consult their family members and communicate their choice. More information on donation and opportunities to register can be found by visiting www.OrganDonor.gov.

Through Medicare, the Federal Government spends nearly $35 billion each year to care for the more than half a million patients with end-stage kidney failure in the United States. Increasing accessibility to organs can save lives while helping to defray overall healthcare costs. As we work to get more people off of the waiting list and into the operating room for a transplant, we are continuing to invest in researching new and innovative ways to address this critical issue. Over the span of three recent years, we invested nearly $3 billion into regenerative medicine research, and we are making great strides in advancing treatment and improving technological capabilities. Additionally, we have opened new doors of collaboration with businesses, universities, and foundations to progress our prevention, diagnosis, and treatment of infectious diseases. Our Nation has taken bold steps in recent years, and we will continue working to reduce the organ waiting list by building on our efforts to utilize regeneration and other methods for ensuring a balance between the supply and demand of vital organs.

Last year, the United States exceeded 30,000 annual organ transplants for the first time. Progress has been made and great promise exists, but much work remains to help the more than 120,000 Americans on the organ waiting list. This month, let us remember those we have lost and provide support to all who continue to wait and hope. Across government, industry, academia, private organizations, and the medical and philanthropic communities, we must all do our part to lift up donors, donor families, and patients by supporting efforts to shorten the organ waiting list. Together, we can improve and save lives by celebrating those who give of themselves—whether as living donors or as registered donors—to provide the greatest gift there is to offer.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2016 as National Donate Life Month. I call upon health care professionals, volunteers, educators, government agencies, faith-based and community groups, and private organizations to join forces to boost the number of organ, eye, and tissue donors throughout our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of April, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2016–08077
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Presidential Documents

Proclamation 9416 of April 1, 2016

National Public Health Week, 2016

By the President of the United States of America

A Proclamation

During National Public Health Week, we join together to enhance public health—the foundation of our security and well-being—here at home and around the world. By supporting health professionals and embracing our obligations to promote public health and protect our planet, we can uphold our shared responsibility to preserve the promise of a happy and healthy life for our children and grandchildren.

Ensuring all Americans have access to quality, affordable health insurance is imperative for maintaining our public health, and I am proud that 6 years after I signed it, the Affordable Care Act has extended the peace of mind that comes with health coverage to 20 million Americans. First Lady Michelle Obama's *Let's Move!* initiative is encouraging more physical activity and nutritious food choices for our Nation's youth, engaging parents and kids in the work of building stronger, healthier communities. To spare more American families heartbreak, I have proposed over 1 billion dollars in new funding to address prescription opioid abuse and heroin use, a public health issue that has taken a devastating toll on too many. We are also striving to promote mental health as an essential component of overall health, helping ensure access to mental health care and services and working to prevent suicide. And because public safety is a critical component of addressing public health, I announced new, commonsense steps this year to help address our country's epidemic of gun violence and keep our neighborhoods safe.

Just as we must sustain a healthy world today, we must do everything in our power to preserve it for those who will inherit it. Climate change has a profound impact on our public health, contributing to intensified smog, an extended allergy season, the spread of diseases into new regions, and greater and more acute incidence of asthma. Last year, the White House hosted a Summit on Climate Change and Health to expand awareness of the real threat a changing climate poses to our health and to focus on vulnerable groups who may face more serious challenges adapting to climate change. No community is immune to this reality, nor can any nation cordon itself off from climate or the air we share. That is why last year, along with nearly 200 countries from around the world, the United States negotiated the Paris Agreement—the most ambitious climate change agreement in history that commits all participating parties to putting forward climate targets of growing stringency to reduce global greenhouse gas emissions. Adopting this agreement for an international framework builds on domestic actions we have already taken to invest in clean energy, reduce our carbon emissions, and transition to a cleaner, healthier, and more sustainable future.

Like the threat of climate change, other public health challenges—like infectious diseases—cannot be addressed by any one nation alone. In an increasingly interconnected world, we face new trials that demand international attention. My Administration is working with our international partners to combat antibiotic-resistant bacteria. We also launched the Global Health Security Agenda, which aims to strengthen all countries' public health systems and stop the spread of disease outbreaks by ensuring nations from around the world have the capacity to prevent, detect, and respond to biological threats to our health and safety. Already, this cooperation is helping us confront the spread of the Zika virus.

America is built on the notion that we are our brothers' and our sisters' keepers, and that we all have certain obligations to one another. Never is that idea truer than when ensuring the health of the world our children will live in long after we are gone. This week, let us treat every child as if they are our own by accepting our responsibilities to leave them with a healthier, cleaner planet than we have, and let us continue reaching for a brighter, more secure future for all the world's people.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 4 through April 10, 2016, as National Public Health Week. I call on all citizens, government agencies, private businesses, non-profit organizations, and other groups to join in activities and take action to improve the health of our Nation.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of April, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

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Presidential Documents

Proclamation 9417 of April 1, 2016

World Autism Awareness Day, 2016

By the President of the United States of America

A Proclamation

Every person deserves the chance to reach for their highest hopes and fulfill their greatest potential. On World Autism Awareness Day, we reaffirm our dedication to ensuring that belief is a reality for all those who live on the autism spectrum—including 1 in 68 children. And we uphold our obligation to help make sure every man, woman, and child, regardless of ability or background, is accepted for who they are and able to lead a life free from discrimination and filled with opportunity.

From home to school and in businesses and communities around the world, people living with autism spectrum disorder contribute in immeasurable ways to our society. They remind us each day that every person is born with unique talents and should be treated with respect, play an active role in planning for their futures, and feel empowered to fully participate in and contribute to their communities. When those with autism have access to equal opportunities, we all do better, and that begins with making sure our country lives up to its commitment to ensure all things are possible for all people.

Individuals with autism are just as deserving of the peace of mind that comes with having quality, affordable health insurance as anyone else. The Affordable Care Act helps ensure no person is prevented from obtaining health coverage simply because they live with a preexisting condition like autism, and it requires most plans to cover recommended preventive services—including critical screenings that test for autism in children. My Administration is dedicated to ensuring educational opportunities for autistic students are worthy of their extraordinary potential and to providing Americans with autism the chance to earn good jobs and hone their skills and talents. We are working to break down barriers to competitive, integrated employment for people with disabilities, including people with autism. We are also promoting inclusivity for kids with autism in high-quality, early childhood education programs. In 2014, I signed the Autism CARES Act, which supports autism-related research and helps us to better understand the particular challenges faced by students and young adults living on the autism spectrum. And this month marks 3 years since my Administration launched the BRAIN Initiative—a collaborative effort by Federal agencies, philanthropies, universities, foundations, and others in the medical and scientific communities that aims to accelerate our work to solve some of the most intricate mysteries of human brain function and reveal new insights into conditions like autism. In my most recent budget proposal, I was proud to support increased funding for this important initiative.

Americans with autism play an important role in our national story, and in their daily lives they embody the belief at the heart of our founding: that in America, with hard work and equal access, all people can realize their aspirations. Today, and every day, let us reach for a future in which no person living on the autism spectrum is limited by anything but the size of their dreams—one in which all people have the opportunity to live a life filled with a sense of identity, purpose, and self-determination.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2, 2016, as World Autism Awareness Day. I encourage all Americans to learn more about autism and what they can do to support individuals on the autism spectrum and their families, and to help shape a world in which all people, including those with autism, are accepted for who they are.

IN WITNESS WHEREOF, I have hereunto set my hand this first day of April, in the year of our Lord two thousand sixteen, and of the Independence of the United States of America the two hundred and fortieth.

Presidential Documents

Notice of April 4, 2016

Continuation of the National Emergency With Respect to Somalia

On April 12, 2010, by Executive Order 13536, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the deterioration of the security situation and the persistence of violence in Somalia, acts of piracy and armed robbery at sea off the coast of Somalia, which have repeatedly been the subject of United Nations Security Council resolutions, and violations of the arms embargo imposed by the United Nations Security Council.

On July 20, 2012, I issued Executive Order 13620 to take additional steps to deal with the national emergency declared in Executive Order 13536, in view of United Nations Security Council Resolution 2036 of February 22, 2012, and Resolution 2002 of July 29, 2011, and to address: exports of charcoal from Somalia, which generate significant revenue for al-Shabaab; the misappropriation of Somali public assets; and certain acts of violence committed against civilians in Somalia, all of which contribute to the deterioration of the security situation and the persistence of violence in Somalia.

Because the situation with respect to Somalia continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, the national emergency declared on April 12, 2010, and the measures adopted on that date and on July 20, 2012, to deal with that emergency, must continue in effect beyond April 12, 2016. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13536.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

THE WHITE HOUSE,
April 4, 2016.

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